EXHIBIT III.6

EXPERT REPORT

Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances

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Prepared by
James E. Rafalski
37637 Five Mile Road #278
Livonia, MI 48154

Table of Contents

List of Schedules

I. QUALIFICATIONS AND EXPERIENCE

Statement of Qualifications

- 1999 graduate of Eastern Michigan University with a degree in Public Administration.
- 26 years of law enforcement experience.
- Retired in 2002 as an Executive Lieutenant with the Romulus Police Department.
- Drug Enforcement Administration Diversion Investigator assigned to the Detroit Divisional Office from September 2004 through retirement in June 2017. Diversion Investigators are responsible for several different types of investigations including regulatory investigations, state-action related investigations, pre-registration application investigations, civil investigations, administrative investigations, and criminal investigations. In 2011 Detroit DEA management restructured the responsibilities of the diversion investigators in the Detroit Divisional Office. At that time, Mr. Rafalski's primary responsibility was to conduct administrative, civil, and regulatory investigations of DEA registrants.
- Successfully completed the following DEA training: Basic Diversion Investigator School (2004), Distributor Briefing/Training (2008), Advanced Diversion Investigator School (2009), Comprehensive Regulatory Investigation Training (2010), Diversion Leadership School (2011), Advanced Diversion Investigator School (2015).
- Participated as a DEA Instructor in the design and presentation of the following training programs: Task Force Officers Training and Orientation, Detroit, Michigan (January 2009), Basic Narcotics Training, Macomb Police Academy, Clinton Township, Michigan (April 2009), U.P. Prescription Diversion/Asset Forfeiture Class, Marquette, Michigan (July 2009 and September 2010), and Basic Narcotic Investigator Course, Richmond, Kentucky (May 2010). Prescription Drug Diversion, Gaylord, Michigan (2015)

Awards

- Maintained a performance rating of "Outstanding" from 2005 to 2016.
- Received DEA performance awards from 2009 to 2015 and in 2017.
- Received an award from the Detroit Federal Executive Board in 2013 for exemplary public service to the DEA.
- DEA Administrator's Award for the investigation of the Harvard Drug Group.

- In June of 2013 and September of 2017 he received recognition from the United States Attorney's Office, Eastern District of Michigan for the Harvard Drug Group and Mallinckrodt LLC

Significant Investigations

- **2004 -2008 Investigation of Dr. Leo Ognen**
  - Criminal opioid investigation related to improper prescriptions.
  - Led to the creation of prescribing database utilized in Ohio.
  - Conducted interviews with employees of pharma companies.
  - Resulted in conviction and incarceration.

- **2006 – 2011 Investigation of Dr. Sohrab Shafinia, D.O.**
  - Criminal opioid investigation of conspiracy to possess controlled substances with intent to distribute.
  - Investigation led to the identification and conviction of an organized prescription drug ring.
  - Extensive reviews of Michigan Automated Prescribing Records (MAPS)
  - Conducted interviews, surveillance, recruiting and utilizing cooperating individuals, as well as undercover activities.
  - Investigation led to the identification and conviction of the responsible pharmacist.

- **2006 – 2008 Investigation of Dr. Louis Cannella, M.D.**
  - Criminal opioid investigation related to improper prescriptions.
  - Extensive reviews of Michigan prescription monitoring program records.
  - Led to the creation of a Wisconsin prescription database.
  - Conducted numerous interviews of witnesses and defendants, surveillance, recruiting and using cooperating individuals, as well as other investigative activities.
  - Resulted in conviction and incarceration.

- **2006 Regulatory Investigation of Walgreen, Perrysburg, Ohio**
  - Unannounced regulatory investigation related to ensure compliance with regulations and record keeping involving controlled substances.
  - Conducted an accountability audit, record-keeping review, and security investigation.
  - Resulted in the issuance of a Letter of Admonition for inadequate SOMS.

- **2007 Regulatory Investigation of Lake Erie Medical Supply**
  - Regulatory investigation related to repackaging, relabeling and distribution of controlled substances mainly to physicians and medical offices.
  - Recommended a distributor briefing at DEA headquarters in November 2008 to reiterate regulatory requirements to registrants.

- Attended the November 2008 distributor briefing presented by other Diversion Investigators.

- **2010 – 2011 Administrative Investigation of The Harvard Drug Group**
  - Conducted a review of ARCOS data to identify any unusual patterns of distribution of oxycodone to Florida pain clinics.
  - Conducted extensive review of company records and policies, controlled substance order forms, DEA Form 222s, and interviews of employees.
  - Conducted review of chargeback system.
  - Investigation led to an Order to Show Cause in June of 2010 for among other things, developing work around as to not trigger SOMS.
  - Investigation concluded with entry of an Administrative Memorandum of Agreement that remained in effect for three years.

- **2010 – 2013 Administrative Investigation of Masters Pharmaceutical**
  - Met with and interviewed employees and initiated an on-site investigation.
  - Served several DEA Administrative subpoenas and obtained 21 customers files to review.
  - Reviewed customer files which contained customer due diligence including but not limited to: questionnaires, on-site investigation reports, written notations, utilization reports, ship to memos, SOMS information, and electronic notations.
  - Investigation concluded with the issuance of an Order to Show Cause.
  - Order to Show Cause resulted in revocation of DEA registration which was affirmed by United States Court of Appeals for the District of Columbia Circuit.

- **2010 – 2017 Administrative Investigation of Mallinckrodt L.L.C.**
  - Administrative investigation begun in response to information related to a chargeback program based on other investigations.
  - Reviewed the chargeback discount program and transactional information involved in the program, which included the purchasers name, address, type and strength of drug, and date of transaction.
  - The investigated chargeback data contained information that allowed Mallinckrodt to see the geographic distribution of their products, the volume and size of purchases.
  - Chargeback data also disclosed some pharmacies and/or practitioners utilizing multiple distributors to purchase the same product in large quantities.
  - Through an administrative subpoena requested documents related to suspicious order system and related policies, related compliance policies, chargeback data, customer files, internal and external communications to include emails, written correspondence, and notes.

- Administrative investigation resulted in an Administrative Memorandum of Agreement that remained in effect for three years.

As a DEA Diversion Investigator with 13 years of experience (2004-2017), I am uniquely qualified to offer expert opinions regarding compliance with federal regulations governing the distribution of controlled substances including oxycodone and hydrocodone. I am familiar with the DEA Diversion Investigators Manual and received training from the United States Department of Justice on suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders and the due diligence required before shipping an order flagged as suspicious. I directly participated in the successful prosecution of Masters Pharmaceutical which resulted in a case opinion from the highest federal court in the country (to date). I led the first action that led to a memorandum of agreement with a manufacturer for failure to maintain effective controls to prevent diversion and failing to design and operate an adequate suspicious order monitoring system.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty that there was a systematic, prolonged failure over many years by the defendant manufacturers and distributors to maintain effective controls against diversion of legitimate opioid prescriptions into the illicit market.[1] I am further of the opinion that this systematic failure was a substantial cause of the opioid epidemic plaguing the country and specifically in Cuyahoga County and Summit County. I am prepared to testify regarding the regulatory duties imposed by the CSA and federal regulations. I have been asked to review the documents produced by the defendants and depositions taken in MDL2804 and offer opinions regarding statutory and regulatory compliance.

I offer my opinions herein to a reasonable degree of professional certainty. I believe the facts stated herein are true and accurate and based on the record provided to me. I understand that the defendants continue to supplement discovery and have disclosed tens of millions of documents. I have relied upon the defendant's answers to Combined Discovery Requests (served on July 1, 2018) as a basic outline for evidence of compliance to reach my opinions.

I am being compensated at the rate of $300.00 per hour for the time I have spent related to this report. The hourly rate for my time spent testifying is $500.00 per hour. I have not previously provided expert testimony at trial or deposition. I have not authored any publications or articles. In addition to the documents and testimony cited within my report, I have also reviewed documents identified in the attached Schedule I.

[1] I provide all opinions in this report with a reasonable degree of professional certainty.

II. STANDARDS

A. STATUTORY DUTY.

Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market. 21 U.S.C.A. § 823(b)(1) [1970].

The Controlled Substances Act ("CSA") and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971 (2006); 21 C.F.R. §§ 1300–1321 (2009). The main objectives of the CSA are to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels. To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. The CSA categorizes all controlled substances into five schedules. The drugs are grouped together based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body. Each schedule is associated with a distinct set of controls regarding the manufacture, distribution, and use of the substances listed therein. The CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.[2]

The CSA authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market.[3] Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA.[4]

The CSA provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain ***illegal***.[5] "Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic."[6]

Distributors of Schedule II drugs—controlled substances with a "high potential for abuse"[7] – must maintain "effective control against diversion of particular controlled substances into other

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[2] *Gonzales v. Raich*, 545 U.S. 1, 12–14 (2005) (internal citations omitted).

[3] H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970); *see* 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880.

[4] 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

[5] 1970 U.S.C.C.A.N. 4566, 4569 (emphasis added).

[6] *United States v. Moore*, 423 U.S. 122, 135 (1975).

[7] 21 U.S.C. §§ 812(b), 812(2)(A)-(C)

than legitimate medical, scientific, and industrial channels."[8] The CSA is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a "closed" system of drug distribution for legitimate handlers of such drugs. **Such a closed system is intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[9] The CSA seeks, through appropriate regulation of the manufacture and distribution of drugs, to reduce the availability of drugs subject to abuse except through legitimate channels of trade and for legitimate uses.[10]

Based on my review of all the relevant documents and testimony taken in this case (MDL 2804) it is my opinion to a reasonable degree of professional certainty that the multiple distributors servicing Cuyahoga County and Summit County failed to maintain effective control against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels in violation of 21 U.S.C.A. § 823(b)(1). The bar graphs included as Figures 1 and 2 in Schedule II evidence the volume of hydrocodone and oxycodone distributed into Cuyahoga County and Summit County from 1996 to 2018.

B. REGULATORY DUTY

Each distributor "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[11]

This regulatory duty has been defined to include the following obligations:

> The "***security requirement***" at the heart of this case mandates that distributors "design and operate a system" to identify "suspicious orders of controlled substances" and report those orders to DEA (the ***Reporting Requirement***). 21 C.F.R. § 1301.74(b). The Reporting Requirement is a relatively modest one: It requires only that a distributor provide basic information about certain orders to DEA, so that DEA "investigators in the field" can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out "potential illegal activity." *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007). Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some

[8] 21 U.S.C. § 823(b)(1).

[9] 1970 U.S.C.C.A.N. 4566, 4571-72.

[10] 1970 U.S.C.C.A.N. 4566, 4574.

[11] 21 C.F.R. § 1301.74(b) [1971]

> "due diligence" and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the ***Shipping Requirement***).[12]

The regulatory duty is not difficult to follow and understand. As one who voluntarily applies to become a registrant must submit an application and undergo a pre-registration investigation. The pre-registration investigation involves a through onsite inspection of the registrant's facilities as well as extensive discussions of the applicable regulations and the security requirements that must be followed. While there are numerous requirements related to registration, my opinions focus on the following compliance requirements:

- Maintain effective controls to prevent the diversion of controlled substances into "other than legitimate medical, scientific, and industrial channels";
- "Design and operate" a system to identify suspicious orders; and
- Report suspicious order "when discovered."

C. MDL2804 Discovery Ruling 12

The Court in MDL2804 issued a discovery ruling (Discovery Ruling 12) which outlines the statutory and regulatory duties imposed by federal law upon distributors of controlled substances.[13] The ruling addresses the following legal standards:

> Distributors of opioids are required to "'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA (the Reporting Requirement)." *Masters Pharmaceutical*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 C.F.R. § 1301.74(b)). Federal regulations explain that "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). Thus, an order for opioids received by a distributor from a retail pharmacy may qualify as "suspicious" for any of a number of different reasons.[14]

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[12] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212–13 (D.C. Cir. 2017) (emphasis added).

[13] See Discovery Ruling No. 12 regarding Suspicious Order Interrogatory [Doc. 1174].

[14] "Of course, an order may be suspicious for other reasons, even if it doesn't fit the Monthly Total Rule, such as that the pharmacy-customer "submitted more order forms in a 30-day period than it had in any of the prior six calendar months [the 'Order Form Rule'], or if the timing of the order did not comport with the customer's general ordering pattern over those six months [the 'Order Timing Rule']." *Id.* There are many other algorithms a distributor could use to identify opioid orders as suspicious, including: (1) the order for the opioid was placed within 30 days of an earlier suspicious order for the same opioid (the "Consecutive Order Rule"); (2) the order for the opioid was placed within 30 days of an order for the same opioid from a different distributor (the "Multi-Distributor Rule"); (3) the percentage increase in the amount of opioid ordered exceeded a certain threshold (the "Percentage Increase Rule"); or (4) the amount of opioid ordered exceeded by some threshold the amounts ordered by other similar or nearby pharmacies ("the Pharmacy Comparison Rule").

"*See also Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) ("a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy that engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious."); *id.* at *55478 (noting that "suspicion" is a low bar: it "is simply a far lower standard of

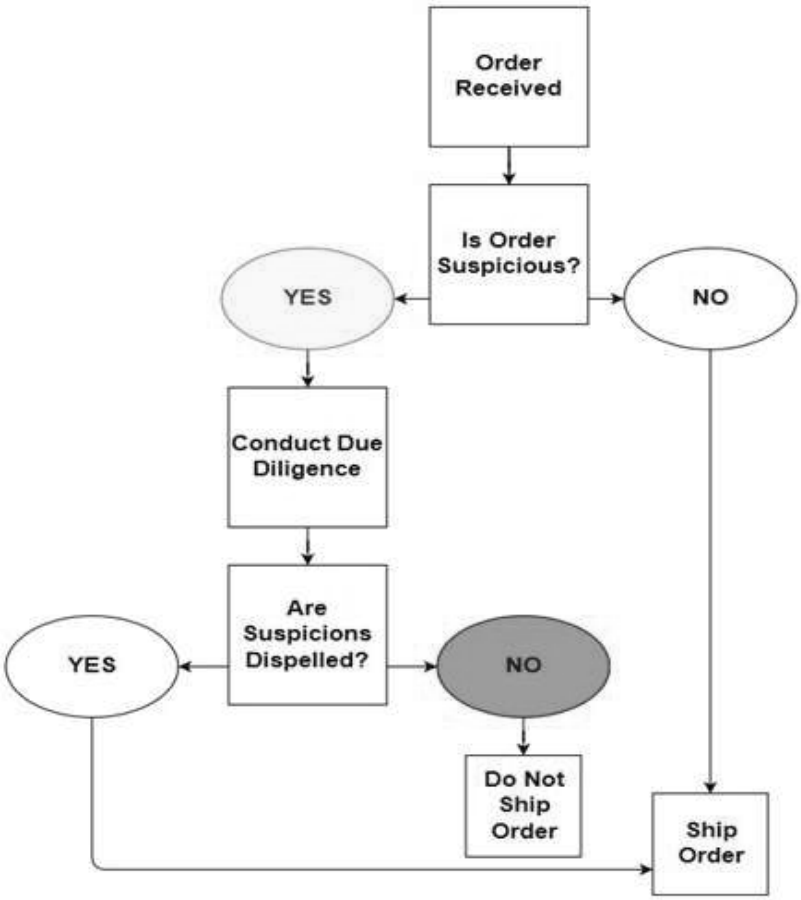
The simplest example is that a given order for an opioid may be suspicious if it was of "unusual size" – say, an order that pushed a pharmacy's monthly total number of opioid doses to exceed the monthly totals the same pharmacy had ordered in the prior six months. The Order refers below to this algorithm as the "Monthly Total Rule." (*Masters Pharmaceutical* described the "Monthly Total Rule" as follows: an order is suspicious if "that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months." *Id.* at 213.)

As noted, once it has identified a suspicious order, a distributor is required to report it to the Drug Enforcement Agency ("DEA"). *See* 21 C.F.R. §1301.74(b) ("The [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the [distributor]."). Furthermore, having received a suspicious order, the distributor "must make one of two choices: decline to ship the [suspicious] order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Id.* at 212–13. Of course, a distributor's due diligence efforts must be thorough: "the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed." *Masters Pharmaceuticals, Inc.*, Decision and Order, 80 Fed. Reg. 55418-01 at *55477 (DEA Sept. 15, 2015) (hereinafter, "*Decision and Order*"). Indeed, the DEA may revoke a distributor's certificate of registration as a vendor of controlled substances if the distributor identifies orders as suspicious and then ships them "without performing adequate due diligence." *Masters Pharmaceuticals*, 861 F.3d at 212.[15]

proof than whether it is 'likely' that the circumstance exists," and "the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.")" Discovery Ruling No. 12, fn 2.

[15] Discovery Ruling No. 12 [Doc. 1174]. *See also*, *id.*, at n.3 ("The *Decision and Order* was a final order entered by the DEA revoking Masters Pharmaceutical's certificate of registration, without which Masters Pharmaceutical could not sell controlled substances. In *Masters Pharmaceutical*, the D.C. Circuit Court of Appeals denied a petition for review, leaving intact the DEA's analysis and conclusion in the *Decision and Order*.")

The Order noted the "legal authorities reviewed above leave unclear exactly when an order is deemed suspicious, and thus when a distributor is required to inform the DEA that it received a suspicious order. The following flowchart illustrates the issue."[16]



This flowchart shows how a distributor's Suspicious Order Monitoring System must work and diagrams the process a distributor must undertake when it receives a suspicious order. Notably, there is a "yellow light" (caution) and a "red light" (stop) in the process. When a distributor first identifies an order as suspicious, this is a "yellow light" – it cannot ship the order without doing some investigation. If that investigation does not "dispel all red flags indicative that a customer is engaged in diversion," then the distributor gets a "red light" and must not ship the order. *Masters Pharmaceutical*, 861 F.3d at 222. Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ("SOMS"), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence

[16] *See* Discovery Ruling No. 12 issued December 9, 2018 at page 5.

efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; it is free to design its SOMS using any algorithms and rules it believes will get the job done.

With regard to the Reporting Requirement, it is not entirely clear whether a distributor's obligation to inform the DEA attaches: (1) when the "yellow light" flashes – that is, when the distributor first identifies an order as suspicious; or (2) only after the "red light" flashes – which would mean a distributor does not have to inform the DEA it received a suspicious order if investigation shows the order was legitimate, after all. Indeed, the authorities cited above provide support for each approach, as shown by the following quotations.

"Red Light"

- "[I]f, ***even after investigating the order***, there is any remaining basis to suspect that a customer is engaged in diversion; the order must be deemed suspicious and the Agency must be informed. *Decision and Order*, 80 Fed. Reg. at *55478.

- "DEA regulations expressly provide that deviations in size, frequency, or pattern are the sort of indicia that give rise to a suspicion and, ***unless the suspicion is dispelled***, the obligation to report. *Masters Pharmaceuticals*, 861 F.3d at 215 (citing *Decision and Order*, 80 Fed. Reg. at *55,479; and 21 C.F.R. §1301.74(b)).

"Yellow Light"

- "***Once a distributor has reported a suspicious order***, it must make one of two choices: decline to ship the order or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order (the Shipping Requirement)." *Masters Pharmaceutical*, 861 F.3d at 212–13.[17]

In other words, the Court determined it is unclear whether an order is "suspicious" (and so must be reported to the DEA) as soon as a distributor's SOMS flags it as suspicious, or only after due diligence fails to dispel any suspicion. In any event, it is clear that distributors are required to identify suspicious orders from pharmacies and cannot ship those orders unless they conduct "due diligence" that determines those orders are not likely to be diverted. Further, distributors are required to report suspicious orders to the DEA upon discovery.

[17] Discovery Ruling No. 12 [1174].

D. ARCOS/DADS

The Automated Records and Consolidated Orders System/Diversion Analysis and Detection System (ARCOS/DADS)[18] system is used to track and report the transfer of pharmaceuticals and to detect potential diversion. This system of records is maintained pursuant to the reporting requirements of the Comprehensive Drug Abuse Prevention and Control Act of 1970[19] and to fulfill the United States treaty obligations under the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances of 1971.[20]

The Automation of Reports and Consolidated Orders System (ARCOS) is the automated system developed by DEA to monitor selected controlled substances. ARCOS software enables the government to maintain a current and historical record of selected controlled substance inventories and transactions from the point of manufacture to the point of sale, distribution, or other disposition, and finally, to the dispenser level.[21]

The information contained in the ARCOS system consists of documentation of individual business transactions between individuals who handle controlled substances at every level, from manufacturers down to the pharmacies. Records include copies of controlled substances inventories, drug codes, deletion and adjustment reports, sales, and purchase orders, and includes, but not limited to the date of the transaction, the name, quantity, and quality of the chemicals/substances purchased or dispensed, the parties to the transaction, NCD code, and the DEA registrant numbers. This information provides an audit trail of all manufactured and/or imported controlled substances.

All automated data files associated with ARCOS/DADS are maintained in the Department of Justice Data Center and the Drug Enforcement Administration Data Center and the system is

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[18] "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.). by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts. *See* United States Department of Justice, Drug Enforcement Administration, Diversion Control Division, Automation of Reports and Consolidated Orders System (ARCOS), *Background: What is ARCOS and What Does it Do?*, https://www.deadiversion.usdoj.gov/arcos/#background (last visited September 7, 2017)

[19] (21 U.S.C. 826(d))

[20] 69 FR 51104-02.

[21] *See* ARCOS Registrant Handbook, United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control, Section 1.1.1, *ARCOS Defined* (Version 1.0 August 1997).

located at Drug Enforcement Administration, 700 Army Navy Drive, Arlington, VA 22202. 69 FR 51104-02.

The ARCOS/DADS system uniquely has access to ***all*** of the data submitted by each DEA registrant from the across the country.[22] These distribution transactional records are compiled by the DEA through a portal and the data is compiled by DEA in accordance with law for determining quota, distribution trends, internal audits, inspection, investigations and other analyses.[23] Additionally, the DEA provides internet access to summary data from this system.

The DOJ/DEA disclosed the national ARCOS database to the Plaintiffs' Executive Committee (2006-2014) and that additional transactional data was independently disclosed by some of the defendants. Both sets of data were then uploaded to a database managed by Craig J. McCann, PhD, CF, of Securities Litigation and Consulting Group, Inc. ("SLCG") (retained as an expert by the PEC). I have relied upon data derived from and provided by SLCG in the formulating of specific requests.

The ARCOS data, defendant transactional data, and the SLCG reports generated therefrom are consistent with the types of data, facts, information, and reports I would typically rely on in conducting the analysis and reaching the opinions contained herein. I am very familiar with the ARCOS data and defendant transactional data and have experience analyzing the data and reports generated therefrom. I have reviewed SLCG's methods and reports and they are consistent with my understanding, based on my experience, of how the data should be analyzed.

E. DEA DIVERSION INVESTIGATOR'S MANUAL.

The DEA published a manual which provides further guidance related to the statutory and regulatory duties. Portions of the manual have previously been publicly available and accurately set forth the charge for DEA investigator as follows:

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. ***The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.*** An

[22] The DEA maintains the Automation of Reports and Consolidated Orders System ("ARCOS"), an official automated comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture through commercial channels to the point of sale or distribution at the dispensing/retail level. Drug wholesalers do not have access to the ARCOS data or to the data of other wholesalers and distributors. *Keysource Med., Inc. v. Holder*, No. 1:11-CV-393, 2011 WL 3608097, at *2 (S.D. Ohio Aug. 16, 2011).

[23] https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion or to registrants against whom previous action has been taken. In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.[24]

Importantly, the DEA does not approve or disapprove supplier shipments of controlled substances. The responsibility for making the decision to ship rests with the supplier.[25] [26]

F. DEA DISTRIBUTOR INITIATIVE BRIEFINGS.

In August 2005, Drug Enforcement Administration designed and implemented the DEA Distributor Initiative. The initiative was in response to the growing number of rogue Internet pharmacies illegally dispensing controlled substances and their pattern of purchasing extremely large amounts of a limited type of controlled substances from distributors. This program consisted of an individual meeting between the DEA and distributors to re-iterate to DEA registrants their responsibilities under the Controlled Substances Act and Code of Federal Regulations and to discuss current trends and methods of diversion.

In February 2014, at a conference in North Carolina, DEA Deputy Assistant Administrator Joseph T. Rannazzisi reported that the DEA had conducted distributor briefings to 81 registrants that had a total of 233 registered locations. The DEA has produced in discovery summaries of some of these meetings as follows:

Memorandum, Meeting with Cardinal Health, Inc. Concerning Interact Pharmacies on August 22, 2005;[27]

Memorandum, Conference Call with. Mr. John. Gilbert of McKesson Corp. on November 28, 2005;[28]

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[24] *See* DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176914 at 01176957) ; *see also* DEA Diversion Manual (1990) (CAH_PRIORPROD_DEA_01176247 at 01176301); DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317 at 00953396, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("By its very nature, an order is a request to purchase controlled substances and has not yet been filled. Reporting a filled order is potentially allowing controlled substances to be diverted. Therefore, suspicious orders will not be filled.")

[25] See DEA Diversion Investigators Manual (1996) (CAH_MDL2804_02203353, CAH_PRIORPROD_DEA07_01176247); see also DEA Diversion Investigators Manual (2011) (CAH_MDL2804_00953317, CAH_MDL2804_01483146, CAH_MDL2804_01563592) ("DEA field offices will not approve or disapprove a registrant's shipment of controlled substances, nor their procedures for detecting suspicious orders. The responsibility for detecting suspicious orders and making the decision to ship rests solely with the registrant.")

[26] At the request of DEA/DOJ, Plaintiffs have removed a section of this Report based on DEA/DOJ's claim that a claw-back of a document cited in the removed section is forthcoming.

[27] US-DEA-00000352.

[28] US-DEA-00000369.

Memorandum, Meeting Between Office of Diversion Control (OD) and McKesson Corp. on January 3, 2006;[29]

Memorandum, Internet Presentation; with AmerisourceBergen on August 10, 2005;[30] and

Memorandum, Distributor Initiative Briefing with AmerisourceBergen Drug on May 16, 2017.[31]

At these briefings DEA personnel would reiterate the registrant's requirement to maintain effective controls to prevent diversion as required in U.S.C. 21 § 843(e) and 21 C.F.R. § 1301.71(a). During these meetings the DEA specifically focused on discussing 21 C.F.R. § 1301.74(b) which states, "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." DEA also advised the registrant at these meetings that DEA cannot tell a distributor if an order is legitimate or not.[32] The distributor has the responsibility to determine which orders are suspicious and once identified they should report those orders to DEA and should not distribute suspicious orders.[33] Further, it was reiterated that a distributor was advised prior to shipping any order that was determined to be suspicious, the distributor should conduct a due diligence investigation to insure the controlled substances in the order are not likely to be diverted and document their due diligence actions.[34] Failure to do so could result in action against their DEA registration.

G. DEA GUIDANCE LETTER

(September 2006) - Written notification issued to distributors and manufacturers from DEA Deputy Assistant Administrator Joseph T. Rannazzisi.[35]

In September 2006, in response to the nationwide growing health problems involving diversion of controlled substances, DEA Deputy Assistant Administrator Joseph T. Rannazzisi forwarded a letter to all DEA registered distributors and manufacturers. The purpose of the letter

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[29] US-DEA-00000371.

[30] US-DEA-00000147.

[31] US-DEA-00000144

[32] US-DEA-00000352, 00000360.

[33] *Id*.

[34] *See also Novelty Distributors, Inc.,* 73 Fed. Reg. 52,689, 52,669 (Drug Enf't Admin. September 3, 2008) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")

[35] *See* CAH_MDL_PRIORPROD_DEA07_00837645.

was to reiterate the legal duties of distributors as DEA registrants and provide some examples of activities that may be indicative of diversion.

Mr. Rannazzisi's letter referenced 21 U.S.C. 823(e) that restated the requirement that distributors and manufacturers have a legal requirement to maintain effective controls against diversion. Mr. Rannazzisi's letter further cited DEA Regulation 21 C.F.R. 1301.74(b) which states the requirement for a registrant to design and operate a system to disclose suspicious orders of controlled substances and to report suspicious orders to the D.E.A. when discovered. The system should be capable of identifying a suspicious order based on size, pattern and frequency and reporting that order to DEA. Contained in the written notification were a list of circumstances that may be indicative of diversion. Those circumstances listed the following:

a. Ordering excessive quantities of a limited variety of controlled substances

b. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d. Ordering the same controlled substances from multiple distributors.

The written communication also listed some guidance for a distributor by providing some possible inquiries of a customer's business activity that could be indicative of diversion. Mr. Rannazzisi further stated and reiterated:

> The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):
>
> > The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
>
> It bears emphasis that the foregoing ***reporting requirement is in addition to, and not in lieu of the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.***
>
> This, in addition to reporting all suspicious orders, ***a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels***. Failure to exercise such due diligence could, as circumstances

warrant, provide a statutory basis for revocation or suspension of a distributor's registration.[36]

H. JUNE 2007 SOUTHWOOD PHARMACEUTICALS, INC. DISTRIBUTOR CASE

DEA Deputy Administrator Michele M. Leonhart issued an Order on June 22, 2007[37], detailing the revocation of DEA registration for Southwood Pharmaceuticals, Inc ("Southwood"). The Order further denied any pending applications for renewal or modification of registration because of the imminent danger to the public health or safety.

The language contained in this Order clearly re-iterated the requirement for a distributor to have a suspicious order monitoring program. The Order states the following, "a registrant must ''design and operate a system to disclose to the registrant suspicious orders of controlled substances''; suspicious orders must be reported to the local Field Division Office upon discovery by the registrant.[38] Under the regulation, suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.''

This Order also contains a description of the conduct of Southwood causing the revocation of their DEA registration as described in the Order to Show Cause and Immediate Suspension Order of Registration (OTSC/ISO) issued on November 30, 2006. The OTSC/ISO detailed that Southwood distributed controlled substances to customers they knew or should have known were diverting controlled substances. The OTSC/ISO stated Southwood repeatedly supplied excessive quantities of hydrocodone to fifteen pharmacies that were orders of unusual size and frequency as well as substantially deviating from the normal pattern. The OTSC/ISO further stated Southwood never reported any of the orders as suspicious to the DEA.

The OTSC/ISO also stated that Michael Mapes of the DEA conducted a meeting with Southwood by conference call on July 17, 2006. The content of the meeting described in the OTSC/ISO is consistent with the DEA Distributor Program being conducted by the DEA and described in this timeline. During this meeting Mr. Mapes discussed the purchasing activities of several pharmacies who were customers of Southwood. During this meeting Mr. Mapes also provided Southwood with a description of illegal conduct of Internet pharmacies and described factors to consider when assessing customers for diversion. These factors included the size and frequency of order, range of product order, and the percentage of control substances ordered when compared to non-controlled substances. Mr. Mapes further discussed the factors that are required to ensure a prescription is legally prescribed by a physician.

The following statement is contained in the OTSC/ISO, "a pattern of drugs being distributed to pharmacies [which] are diverting controlled substances demonstrates a lack of effective controls against diversion by the distributor" and could lead to the revocation of the distributor's registration." Mr. Mapes further stated, "… any distributor who was selling controlled

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[36] *See id.* (emphasis added).

[37] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

[38] 21 CFR 1301.74(b).

substances that are being dispensed outside the course of professional practice must stop that distribution immediately."[39]

The OTSC/ISO stated Mr. Mapes discussed with Southwood representatives whether it could ship an order which it had reported as suspicious. Mr. Mapes advised Southwood representatives if they reported a suspicious order to the D.E.A. they still needed to make the decision as to whether to ship the order. The OTSC/ISO further detailed that Southwood representatives asked Mr. MAPES whether they should stop shipping controlled substances to the internet pharmacies and Mr. MAPES replied the DEA cannot tell a distributor whether a particular order is legitimate or not, and whether to ship was "a business decision," but Southwood had an obligation to ensure that the controlled substance being distributed were used for legitimate medical purposes.

I. DECEMBER 2007 DEA GUIDANCE LETTER

In December 2007, DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph T. Rannazzisi issued a second letter to all DEA registered distributors and manufacturers restating much of the information contained in the previous letter.[40]

This letter was focused on reiterating the responsibilities of manufacturers and distributors to inform DEA of suspicious orders as required by 21 CFR 1301.74(b)

The letter re-iterated that 21 CFR 1301.74(b) requires a manufacturer or distributor to design and operate a system to disclose to the registrant suspicious order of controlled substances. The letter further notified registrants it is the sole responsibility of registrants to design and operate the system. The letter advised registrants of the following, “Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for report suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The letter also notifies that filing a monthly report of transactions to the DEA, often referred to as excessive purchase reports, does not meet the regulatory requirement to report suspicious orders.

The letter also reiterated the following requirements:

1. 21 CFR 1301.74(b) requires DEA registrants inform the DEA of suspicious order when discovered by the registrant.
2. DEA registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine if the controlled substances are likely to be diverted.
3. The regulation states suspicious orders include orders of an unusual size, deviating substantially from a normal pattern, and orders of an unusual frequency. The criteria are disjunctive and are not all inclusive.

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[39] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 Fed. Reg. 36,487, 36,492(Drug Enf’t Admin. July 3, 2007).

[40] CAH_MDL_PRIORPROD_DEA07_00092296.

4. DEA registrants who routinely report suspicious orders, yet fill these orders without first determining whether the orders are not being diverted may be failing to maintain effective controls against diversion that may result in possible action against their DEA registration.

J. DEA ADMINISTRATIVE ACTIONS

Distributors and manufacturers in this industry regularly monitor DEA administrative actions involving maintenance of effective controls against diversion and failure to identify and/or report suspicious orders. There are many different types of sources that make the details of DEA administrative action available for the industry to review. The type of information available can be a very in-depth article or publications simple as a press releases. Two examples of an in-depth sources of information is the information published in the Federal Register involving DEA cases against Masters Pharmaceutical Inc. and Southwood Pharmaceuticals Inc.

The DEA posts administrative case information on the Internet on their website at www.deadiversion.usdoj.gov. The DEA and Department of Justice also normally issue press releases on administrative actions that subsequently generate media coverage and reviews by law firms. Further, trade organizations like HDA typically publish articles regarding DEA administrative action for review by their members. Typically, when a DEA administrative action occurs, there are several law firms that closely follow the industry and they post articles on their websites that describe the action and offer opinions of future impact to the industry.

Listed below are some of the significant administrative action against distributors and manufacturers for failing to maintain effective controls against diversion and for failing to identify and/or reports suspicious orders:

1. April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement and release agreement with the DEA related to the allegations made by the agency.[41]

2. June 22, 2007, the DEA revoked the Registration of Southwood Pharmaceuticals, Inc. 72 Fed. Reg. 36,487 (Department of Justice; Southwood Pharmaceuticals, Inc.; Revocation of Suspension (July 2, 2007)) on Tuesday, July 3, 2007July 3, 2007, Department of Justice, Drug Enforcement Administration article in the Federal Register, titled, Southwood Pharmaceuticals, Inc.; Revocation of Registration.[42]

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[41] AmerisourceBergen Corporation, *AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of its Orlando Distribution Center's Suspended License to Distribute Controlled Substances*, June 22, 2007, available at http://investor.amerisourcebergen.com/news-releases/news-release-details/amerisourcebergen-signs-agreement-dea-leading-reinstatement-its (last visited March 11, 2019).

[42] *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007)(*also available at* https://www.deadiversion.usdoj.gov/fed_regs/actions/2007/fr07032.htm (last visited March 10, 2019)).

3. November 29, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center which suspended their DEA registration for failure to maintain effective controls against diversion of hydrocodone.[43]

4. December 7, 2007, DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[44]

5. December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center for failure to maintain effective controls against diversion of hydrocodone.[45]

6. January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Health Stafford, Texas Distribution Center for failure to maintain effective controls against diversion of hydrocodone. Cardinal agreed to suspend shipping any controlled substances from the location pending a resolution with the DEA.[46]

7. May 2, 2008, McKesson Corporation agree to pay a $13 million civil penalty and entered into an Administrative MOA with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program.[47]

8. On September 30, 2008, Cardinal Health agreed to pay a $34 million civil penalty and entered into a Settlement and Release Agreement and Administrative Memorandum of

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[43] Cardinal Health, Press Release, *Cardinal Health Receives DEA Order to Temporarily Cease Distribution of Controlled Substances from Auburn Wash. Facility*, November 29, 2007, available at (Source: https://ir.cardinalhealth.com/news/press-release-details/2007/Cardinal-Health-Receives-DEA-Order-to-Temporarily-Cease-Distribution-of-Controlled-Substances-from-Auburn-Wash-Facility/default.aspx (last visited March 11, 2019).

[44] Cardinal Health, Press Release, *Cardinal Health to Cease Distribution of Controlled Substances from Florida Facility,* December 7, 2007, available at https://cardinalhealth mediaroom.com/newsreleasearchive?item=122500 (last visited March 8, 2019).

[45] Drug Topics, "DEA hits third Cardinal Health distribution center," December 21, 2007, available at https://www.drugtopics.com/pharmacy/dea-hits-third-cardinal-health-distribution-center (last visited March 8, 2019).

[46] Drug Topics, "Cardinal caught between DEA and pharmacies over diversion control," April 14, 2008, available at https://www.drugtopics.com/community-practice/cardinal-caught-between-dea-and-pharmacies-over-diversion-control (last visited March 9, 2019).

[47] Settlement and Release Agreement and Administrative Memorandum of Agreement, entered into May 2, 2008, between DEA and McKesson Corporation, available at https://www.dea.gov/sites/default/files/ 2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf (last visited March 19, 2019).

Agreement (MOA) with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The MOA also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances.[48]

9. January 9, 2009, Rite Aid agreed to pay $5 Million in civil penalties to resolve allegations that Rite Aid knowingly filled prescriptions for controlled substances that were not issued for legitimate medical purposes; failed to notify the DEA of significant thefts and losses of controlled substances; failed to maintain or failed to furnish to the DEA upon request records required to be kept under the Controlled Substances Act for a period of two years; and failed to properly execute DEA forms used to ensure the amount of Schedule II drugs ordered by Rite Aid were actually received violations of the Controlled Substances Act in eight states.[49]

10. April 21, 2009, Settlement and Release Agreement and Administrative Memorandum of Agreement between DOJ/DEA and Masters Pharmaceutical Inc.[50]

11. June 15, 2010, Order to Show Cause – Immediate Suspension Order served to The Harvard Drug Group, Livonia, MI.[51]

12. June 10, 2010, DEA suspended Sunrise Wholesale, Inc. from selling controlled substances for supplying excessive amounts of oxycodone to "pill mills."[52]

13. October 13, 2010, settlement was reached between the DEA and CVS Pharmacy, Inc. resolving the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy

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[48] United States Attorney's Office. (October 2, 2008) *Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims That It Failed to Report Suspicious Sales of Widely-Abused Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html (last visited March 10, 2019).

[49] United States Department of Justice, (January 12, 2009) *Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations (last visited March 8, 2019).

[50] Settlement and Release Agreement and Administrative Memorandum of Agreement between DEA and Masters Pharmaceutical, Inc. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Masters%20Pharmaceutical%20-%202009.pdf (last visited March 19, 2019.

[51] Administrative Memorandum of Agreement between DEA and The Harvard Drug Group, LLC dated March 28, 2011. Available at https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20Harvard%20Drug%20Group%20-%202011.pdf (last visited March 19, 2019).

[52] LaMendola, Bob. "DEA accuses Sunrise company of supplying painkillers to 'pill mills.'" Sun-Sentinel. June 22, 2010. Available at https://www.sun-sentinel.com/business/fl-xpm-2010-06-22-fl-drug-wholesaler-stopped-20100621-story.html (last visited March 19, 2019).

distribution center in Southern California. CVS paid a penalty of $75,000,000.00 and forfeited $2.6 million in profits for a total payment of $77.6 million.[53]

14. April 18, 2011, Harvard Drug Group agreed to pay $8,000,000 in civil penalties as part of settlement with DEA related to allegations that Harvard failed to have in place an effective system for identifying suspicious orders of controlled substances, violating the Controlled Substances Act.[54]

15. June 10, 2011, Order to Show Cause and Immediate Suspension Order served on Keysource Medical Inc. Keysource Medical distributed 48 million doses of oxycodone products to Florida Pharmacies.[55]

16. July 6, 2011, Order Denying Plantiff's (Keysource Medical) Motion for Temporary Restraining Order and for Preliminary Injunction.[56]

17. February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone.[57]

18. March 7, 2012, Memorandum of Opinion [Doc. 32] from the United States District Court for the District of Columbia, *Cardinal Health, Inc., vs. Eric H. Holder, Jr.*, Civil Action No. 12-185 (RBW), denying Cardinal's challenge of the DEA's Order to Show Cause and Immediate Suspension of Registration of Cardinal's Lakeland Distribution Center.[58]

19. April 5, 2012, A United States Attorney Office press release stated Keysource Medical agreed to pay a $320,000 fine for failing to guard against diversion of controlled

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[53] United States Attorney's Office. (October 14, 2010) *CVS Admits Illegally Selling Pseudoephedrine to Criminals who made Methamphetamine, Agrees to Pay $77.6 Million to Resolve Government Investigation* [Press Release]. Available at https://www.justice.gov/archive/usao/cac/Pressroom/pr2010/148 html (last visited March 19, 2019).

[54] United States Drug Enforcement Administration. (April 18, 2011) *Michigan Based Pharmaceutical Wholesaler Harvard Drug Group to Pay $8,000,000 in Settlement* [Press Release]. Available at https://www.dea.gov/press-releases/2011/04/18/michigan-based-pharmaceutical-wholesaler-harvard-drug-group-pay-us (last viewed on March 19, 2019).

[55] United States Drug Enforcement Administration. (June 10, 2011) *Cincinnati Pharmaceutical Supplier's DEA License Suspended* [Press Release]. Available at https://www.dea.gov/press-releases/2011/06/10/cincinnati-pharmaceutical-suppliers-dea-license-suspended (last visited March 11, 2019).

[56] *Keysource Medical, Inc., v. Attorney General of the United States, et al.*, No. 1:2011cv00393, *Order Denying Plaintiff's Motion for Temporary Restraining Order and for Preliminary Injunction* [Doc. 22], available at https://law.justia.com/cases/federal/district-courts/ohio/ohsdce/1:2011cv00393/147299/22/ (last visited March 11, 2019).

[57] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[58] Copy of Order available at https://www.govinfo.gov/content/pkg/USCOURTS-dcd-1_12-cv-00185/pdf/USCOURTS-dcd-1_12-cv-00185-0.pdf (last visited March 19, 2019).

substances. and states Keysource Medical agreed to voluntarily surrender their DEA registration in September 2011.[59]

20. May 14, 2012, Cardinal Health entered into an Administrative MOA with the DEA, which, among other things, stipulated that its compliance with the terms of the 2008 MOA were inadequate in certain respects and that its Lakeland, Florida Distribution Center's DEA registration would be suspended for two years.[60]

21. March 28, 2013, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc and Oklahoma CVS Pharmacy, L.L.C., to resolve claims that CVS violated the CSA by: (1) filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.00.[61]

22. In July, 2013, the DEA initiated a regulatory investigation at CVS Indiana. After the investigation and after the DEA had informally indicated its displeasure with what it found at CVS, Mark NiCastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. In the correspondence, Mr. NiCastro attempted to explain to the DEA why the CVS Indiana distribution center had never reported a suspicious order and he wrote:

> "In your recent email, you asked for information concerning CVS store orders that have been stopped outside of Indiana. Across the chain, the CVS SOM process has stopped and cancelled orders. I have attached the dates and the offices to which we reported these orders. As we discussed during the DEA audit and during our recent phone call, it is important to remember that CVS is shipping only to its own stores, and there are additional due diligence processes in our pharmacy operations group which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores. This is a primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[62]

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[59] United States District Attorney's Office, Southern District of Ohio. (April 5, 2012) *Cincinnati Pharmaceutical Distributor to Pay $320,000 for Failing to Guard Against Diversion of Controlled Substances* [Press Release]. Available at https://www.justice.gov/archive/usao/ohs/news/04-05-12.html (last visited March 11, 2019).

[60] 2012 Administrative Memorandum of Agreement entered into between DEA and Cardinal Health, CAH_MDL2804_02465982.

[61] CVS-MDLT1-000060822 – 000060829.

[62] *See* NiCastro Depo. at 204-207; Ex. 42.

23. July 17, 2013, Walgreens agreed to pay $80 Million in civil penalties related to allegations that Walgreens was filling numerous prescriptions that Walgreens employees knew, or should have known, were not issued for a legitimate medical purpose.[63]

24. June 19, 2014, In Regards to Masters Pharmaceutical the Administrative Law Judge issued a Recommended Decision in regards to the Order to Show Cause Hearing that occurred on February 24 through 28 and March 3 through 4, 2014. [64]

25. On September 2, 2014, settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement resolved claims against CVS for filling from April 1, 2012 to July 31, 2012, 153 prescriptions at eight different pharmacies, written by Dr. Pedro Garcia during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[65]

26. On May 12, 2015, a settlement was reached among the United States and the DEA and CVS Health and all of its subsidiaries and affiliates. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances into other than21 U.S.C. §823(e)" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.00.[66]

27. On July 24, 2015, a Settlement was reached among the United States and the DEA and CVS Health to resolves claims that from May 1, 2013 through July 30, 2014, CVS failed to keep complete and accurate records of Schedule II controlled substances at a CVS store in Massachusetts in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.11(e)(3)(i), 1304.21, and 1304.22; and that CVS failed to report a March 14, 2014 robbery to the DEA within one business day in violation 21 C.F.R. § 1301.76(b). CVS paid a $50,000 fine.[67]

28. On August 7, 2015, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between March 3, 2010 and August,

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[63] United States Attorney's Office, Eastern District of New York. (July 17, 2013) *Eastern District U.S. Attorney's Office Participates in Record Settlement: Walgreens Agrees to Pay $80 Million in Civil Penalties Under the Controlled Substnaces Act* [Press Release]. Available at https://www.justice.gov/usao-edny/pr/eastern-district-us-attorney-s-office-participates-record-settlement-walgreens-agrees (last visited March 19, 2019).

[64] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[65] CVS-MDLT1-00060907 – 000060914.

[66] CVS-MDLT1-000060796 – 000060804.

[67] CVS-MDLT1-000099702 –000099704.

2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA number (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing practitioners in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[68]

29. September 8, 2015, Masters Pharmaceutical – DEA Acting Administrator Chuck Rosenberg issued a Final Order revoking the DEA registration of Master Pharmaceutical Inc.[69]

30. On December 18, 2015, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of a DEA Inspection that was performed after CVS reported the theft of over 40,000 dosages of controlled substances by two former employees from a Texas CVS pharmacy. The inspection that was started due to theft demonstrated that CVS again failed its CSA obligations. CVS paid a fine of $345,000.00.[70]

31. On December 31, 2015, the DEA issued a letter of admonishment for violations in distributing HCPs at the CVS Indiana distribution center. This DEA finding was the result of the July 2013 investigation. Before the admonishment, Agent Gillen of the DEA sent an email to Mr. Nicastro outlining that CVS Store No. 6880 ordered [redacted] dosage units of hydrocodone between January 1, 2012 and October of 2013. The pharmacy is located in Vincennes, IN with a population of approximately 18,000 people. Additionally, he indicated that Store No. 6757 ordered [redacted] of hydrocodone tablets for Columbus, IN, which has a population of 45,000. Agent Gillen then writes: "Both stores have purchased a large quantity of Hydrocodone given their population."[71]

32. On February 12, 2016, a Settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. In the Settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…" CVS paid a fine of $8,000,000.00.[72]

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[68] CVS-MDLT1-000060847 – 000060855.

[69] *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418-55,501 (Drug Enf't Admin. Sept. 15, 2015).

[70] CVS-MDLT1-00060915-00060921.

[71] *See* CVS-MDLT1-00008014 – 00008015; CVS-MDLT1- 000076135.

[72] CVS-MDLT1-000060805-00060811.

33. June 30, 2016, CCS agreed to pay $3.5 Million to resolve allegations that 50 of its stores violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[73]

34. On October 20, 2016, a Settlement was reached among the United States and CVS Pharmacy, Inc. The Settlement resolved claims from an investigation that the DEA began in January 2016. The DEA investigated two CVS stores in Connecticut. Although the offending conduct occurred after CVS quit distributing HCPs, it is indicative of the overall pattern and practice of CVS. The Settlement resolves claims that CVS failed to keep paper Schedule III-V prescriptions either in a separate prescription file or readily retrievable from other prescription records, which allegedly violated 21 U.S.C. 827(b)(2)(A) and (B) and 21 C.F.R. 1304.04(h)(4) and failed to keep Schedule III-V purchase invoices on at least 31 occasions in separate or in a readily retrievable manner from all other records of the pharmacy, which allegedly violated 21 U.S.C. 827(b)(2)(A) AND (b) AND 21 C.F.R. 1304.04(h)(3). CVS paid a $600,000 fine.[74]

35. December 22, 2016, Consent Order entered into between the United States and Kinray, LLC, a subsidiary of Cardinal Health.[75]

36. December 23, 2016, Cardinal Health agreed to pay a $34 million civil penalty to the DEA to resolve allegations that it failed to report suspicious orders and meet its obligation under the CSA in Florida, Maryland, New York, and Washington.[76]

37. January 5, 2017, McKesson Corporation entered into an Administrative MOA with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[77]

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[73] United States District Attorney's Office, District of Massachusetts. (June 30, 2016) *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions* [Press Release]. Available at https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions (last visited March 19, 2019).

[74] CVS-MDLT1 000060830 – 000060838.

[75] *United States of America v. Kinray, LLC*, Case #16 Civ. 8767-RA. Available at https://www.justice.gov/usao-sdny/press-release/file/920806/download (last visited March 19, 2019).

[76] United States Attorney's Office, Middle District of Florida. (December 23, 2016) *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under (last visited March 19, 2019).

[77] United States Department of Justice. (January 17, 2017) *McKesson Agrees to Pay record $150 Million settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs* [Press Release]. Available at

38. January 18, 2017, Walgreens agreed to pay $200,000 following an investigation by the Massachusetts Attorney General's Office found that Walgreens failed to track the opioid use of high-risk patients in the state's Medicaid program.[78]

39. March 9, 2017, Rite Aid paid $834,200 to the United States to settle claims that Rite Aid pharmacies in Los Angeles, California dispensed and/or recorded controlled substances using a medical practitioner's incorrect or invalid DEA registration number.[79]

40. June 30, 2017, the United States Court of Appeals for the District of Columbia Circuit published an opinion denying the Masters' petition of review and upholding the Final Order.[80]

41. On July 5, 2017, a settlement was reached among the United States and the DEA and CVS Pharmacy, Inc. The Settlement was the result of an investigation began by the DEA as a result of "an increase in the number of thefts and explained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances (*see* 21 C.F.R. §1301.71(a)) and failure to notify DEA of certain thefts or significant losses of controlled substances within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their

https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (last visited March 19, 2019).

[78] Associated Press, "Walgreens to pay $200k, change opioid procedures," The Washington Times, January 19, 2017, available at https://www.washingtontimes.com/news/2017/jan/19/walgreens-to-pay-200k-change-opioid-procedures/) (last visited March 11, 2019).

[79] United States Attorney's Office, Central District of California. (March 9, 2017) *Rite Aid Corporation Pays $834,300 to Settle Allegations of Violating the Controlled Substances Act* [Press Release]. Available at https://www.justice.gov/usao-cdca/pr/rite-aid-corporation-pays-834200-settle-allegations-violating-controlled-substances-act (last visited March 19, 2019).

[80] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

recordkeeping obligations, but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.00.[81]

42. July 7, 2017, Department of Justice/DEA and Mallinckrodt entered into a Memorandum of Agreement to resolve allegations that if failed to maintain effective controls to prevent diversion and to detect and report suspicious orders.[82]

43. January 24, 2018, the U.S. Attorney's Office entered into settlement with Rite Aid for improper sales of the meth precursor pseudoephedrine.[83]

44. On June 15, 2018, a Settlement was reached among the United States and the DEA and CVS Health. The Settlement resolved claims that between February, 2013 and January, 2015, CVS failed to report to the DEA in writing, within one business day of discovery, thefts or significant losses of controlled substances, including hydrocodone, from certain Long Island CVS Pharmacy retail stores, as required by 21 C.F.R. §1301.76(b). CVS agreed to pay a $1,500,000.00 fine. (CVS-MDLT1-000060839 – 000060846).

45. On July 29, 2018, a Settlement was reached the among the United States and the DEA and CVS Pharmacy, Inc., to resolve claims related to a November 2013 inspection of a CVS Pharmacy in Calera, Alabama. The Settlement resolved claims that CVS violated the CSA, as a result of violations of : (1) 21 C.F.R. 1305.13(c) (requirement to record the amount received and/or the date received on DEA 222 forms); (2) 21 C.F.R. 1304.21(a) (requirement to maintain complete and accurate records); and (3) 21 C.F.R. 1304.21(a) and/or (d) (requirement to document the number of packages received or the date package received on Schedule III through V purchase invoices). CVS agreed to pay a $1,000,000 fine.[84]

46. August 21, 2018, CVS agreed to pay $1 Million to settle allegations that CVS stores in Alabama failed to keep adequate records in violation of the Controlled Substances Act.[85]

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[81] CVS-MDLT1 000060856-000060871.

[82] Administrative Memorandum of Agreement between DEA and Mallinckrodt, plc and its subsidiary Mallinckrodt, LLC, dated July 7, 2017. Available at https://www.justice.gov/usao-edmi/press-release/file/986026/download (March 19, 2019).

[83] United States Attorney's Office, Southern District of West Virginia. (January 24, 2018) *U.S. Attorney's Office enters settlement with Rite Aid based on improper sales of meth precursor pseudoephedrine* [Press Release]. Available at https://www.justice.gov/usao-sdwv/pr/us-attorneys-office-enters-settlement-rite-aid-based-improper-sales-meth-precursor (last visited March 11, 2019).

[84] CVS-MDLT1-000060812 –000060821.

[85] United States Attorney's Office, Northern District of Alabama. (August 21, 2018) *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for Violations of the Controlled Substances* [Press Release]. Available at https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act (last visited March 19, 2019)

47. December 31, 2018, the DEA and the Rhode Island Attorney General announced $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums.[86]

K. INDUSTRY GUIDELINES - HEALTHCARE DISTRIBUTION ALLIANCE

A large number of drug distributors and manufacturers are members of The Healthcare Distribution Alliance (HDA), a trade organization that provides industry information, provide guidance on best practices, industry standards, regulation/legal changes, and other related services.

A review of the website for The Healthcare Distribution Alliance (HDA) provided the following history of the organization.[87] The Western Wholesale Druggists' Association (WWDA) was formed on March 15, 1876 and consisted of 95 wholesale druggists. In 1882 the WWDA became the National Wholesale Druggists Association (NWDA) that was representing distribution companies as an advocate in the distribution industry.

In 2000 the NWDA organization was renamed Healthcare Distribution Management Association (HDMA). The website stated the organization changed reflected the "Association's vision of a progressively more efficient and effective distribution system." In 2016 the HDMA changed names to the Healthcare Distribution Alliance (HDA). The website states the following, "Now headquartered in Arlington, Virginia, HDA represents 36 distribution companies — national, regional and specialty — as well as more than 130 manufacturer and more than 50 service provider/international members, respectively. These members serve more than 200,000 licensed healthcare providers, delivering over 15 million lifesaving products to these outlets every day. But just as in 1876, HDA's mission has remained the same, which is to protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices."

NWDA 1984 Suspicious Order Monitoring Policy

A review of Cardinal Health discovery material revealed a thirty-eight page document from 1984 by NWDA which was a draft outline of a suspicious order monitoring system. The documents can be found in the Cardinal Health discovery material in a group of documents that begin with a cover page containing, "NWDA Suspicious Order Monitoring System" with this stamped information, "Received Jun 21 1993 by Folsom."[88]

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[86] United States Drug Enforcement Administration. (December 31, 2018) *DEA and Attorney General Kilmartin announces $300,000 settlement with Rite Aid for filling prescriptions of Schedule III controlled substances in excess of statutory maximums* [Press Release]. Available at https://www.dea.gov/press-releases/2018/12/31/dea-and-attorney-general-kilmartin-announces-300000-settlement-rite-aid (last visited March 11, 2019).

[87] *See* https://www hda.org/ (last viewed on March 20, 2019).

[88] The group of documents described in this section can be found in the Cardinal Health discovery material with a Bates stamp range of CAH_MCL2804_01465723 to CAH_MCL2804_01465761.

The first seven pages of the document describes some of the elements of a suspicious order system. These seven pages do not contain a date indicating when the system was designed. There are two DEA letters in the documents that do identify a date which are letters from the DEA. These DEA letters provide comment and guidance to NWDA in regards to the suspicious order system. The first DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA) and signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA). The letter contained a stamped date of April 27, 1984, which details a meeting between the two on April 13, 1984. This letter stated the DEA reviewed a draft form of the suspicious order monitoring system. This DEA letter contained the following comment:

> The NWDA's draft format for a suspicious order monitoring system provides as excellent framework for distributor registrants to "…design and operate a system to disclose to the registrant suspicious orders of controlled substances." (21 CFR 1301.74(b).) However, I am compelled to note, as I have in our previous discussions, that any automated data compliance processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of the sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes."[89]

The second DEA letter was addressed to Mr. Ronald J. Streck, Vice President of Government Affairs (NWDA), signed by G. Thomas Gitchel, Acting Chief Diversion Operations Section (DEA) that was stamped with a date of May 14, 1984, which appeared to be a follow-up communication from the April 27, 1984 letter. This letter details that there was a NWDA meeting that was attended by DEA employee David Walkup. This DEA letter contained the following comment:

> I want to assure you that DEA fully supports NWDA's effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to a shipment.[90]

The background section of the system details it was created in co-operation with the DEA. Further, the document states that the DEA may be providing some variances and limits that would be incorporated into the suspicious order system.

On page 7 of the suspicious order system document is "Section IX" that contains the following statement: "Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of report these excessive or suspicious orders. DEA has interpreted "orders" to

[89] CAH_MDL2804_01465723, 01465732.

[90] CAH_MDL2804_01465723, 01465734.

mean prior to a shipment." This statement along with the letter from DEA is an important communication that identifies the DEA was requiring the suspicious order system to identify single orders of controlled substances that must report immediately prior to being shipped.

2008 Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Report Suspicious Orders and Preventing Diversion of Controlled Substances.

In 2008 the HDMA posted on their website industry compliance guidelines that were titled, "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances." In the introduction section of the document appeared this comment:

> At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support security of controlled substances they deliver to their customers. Due Diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them flor legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.[91]

On October 17, 2008, DEA Chief Counsel Attorney Wendy H. Goggins sent a written statement to HDMA President and CEO John M. Gray commending the HDMA for their efforts to assist their members in fulfilling the obligations regarding the Controlled Substance Act and corresponding regulations.[92]

The HDMA compliance guidelines document contains a general framework for a basic suspicious order monitoring system.[93] The document contains the following elements with accompanying suggested guidelines:

1. Know Your Customer Due Diligence
2. Monitoring for Suspicious Orders
3. Suspend/Stop an Order of Interest Shipment
4. Investigation of Orders of Interest
5. File Suspicious Order of Interest
6. Employees, Training and Standard Operating Procedures (SOPs)
7. Additional Recommendations
8. Glossary of Abbreviations

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[91] February 10, 2012 Declaration of Joseph Rannazzisi, CAH_MDL_PRIORPROD_DEA12_00014479, 00014512.

[92] CAH_MDL_PRIORPROD_DEA12_00000825.

[93] CAH_MDL_PRIORPROD_DEA12_00000826.

Although there are several areas or concerns which might render a suspicious order monitoring system less effective, the guidance provided by HDMA does contain several key elements that are consistent with compliance with 21 C.F.R. Section 1301.71(a) and 1301.74(b). Some of the keys areas of the guidance are the following:

1. Recommending distributors conduct thorough due diligence investigations that are documented and retained is essential in establishing a customer and providing a history for any further compliance actions or investigations.[94]

2. Guidance for a distributor to develop an electronic suspicious order system as detailed in a standard operation procedure, although not required by regulation, demonstrates HDMA recognizes the manual review of orders for deviations in size, frequency, or pattern would render it ineffective.[95]

3. Separating customers by business activity or class of trade is an essential system element. Further enhancement for monitoring and setting averages would be to form subgroups by the size of the customer.[96]

4. Recommending of placing the controlled substances being monitored into groups or families provides a starting point for setting an average and monitoring. Only monitoring drug families and failing to evaluate the unusual order size, pattern, or frequency of any specific drug within a drug family has a much higher probability of failing to identify diversion of specific highly abused drugs.[97]

5. Thresholds are set as averages shipped to a customer's facility that are consistent with that class of customer. Threshold are recommended to calculated for single orders and average monthly orders per family, per customer, and class of trade. Thresholds should utilize the information obtained in the due diligence investigation. A sales history of a minimum of six months and maximum of 24 months is recommended. Thresholds for new customer accounts should be established at the lowest level indicated by the due diligence investigation. An important component is the periodic review of cumulative orders for the customer to evaluate purchasing trends.[98] Note: The use of a six-month average does not provide a sufficient purchase history for establishing accurate thresholds.

6. A distributor should consider allowing use of alternative criteria, outside of the suspicious order system, to be utilized to identify a suspicious order.[99]

7. On Page 9, Section III in the section titled, SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT, there is clear guidance from HDMA of what action should be taken by

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[94] CAH_MDL_PRIORPROD_DEA12_00000826, 00000829-00000832.

[95] CAH_MDL_PRIORPROD_DEA12_00000826, 00000832.

[96] CAH_MDL_PRIORPROD_DEA12_00000826, 00000833.

[97] *Id*.

[98] *Id*.

[99] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000834.

a distributor when an order exceeds a threshold which is contained in the following statement, "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[100]

8. Recommending if an order meets or exceeds a threshold the distributor examine the order further. The examination aids the distributor in deciding to either fill the order and ship or to continue to hold the order. This section also states, "Further examination will also aid in determining whether the and when to report the order to DEA under 21 C.F.R. Section 1301.74(b)."[101]

9. The following statement is made in regard to an order of interest, "The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest."[102]

12. A customer interview should be conducted in regards to order. Any information provided by the customer should be verified and documented.[103]

13. All investigation conducted by the distributor should be "fully documented," and all records retained in an appropriate section. A critical element of guidance states the following, "The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." The statement should be signed and dated by the reviewer."[104]

15. Order determined to be "suspicious" should be reported immediately upon being so determined.[105]

18. The following guidance was provided for the content of the standard operating policy:

a. Describe how an initial review and investigation will be conducted;

b. Reflect the distributor's and its customers' business conditions;

c. Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;

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[100] *Id*.

[101] *Id*.

[102] *Id*.

[103] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000835.

[104] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000836.

[105] *Id*.

d. Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";

e. Define a process for reporting to DEA under 21 C.F.R. Section 1301.74(b); and

f. Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.[106]

19. If a distributor concludes an order is suspicious after conducting an investigation it is recommended the distributor make a determination whether they will subject future orders from the same customer for the same drug product to more rigorous scrutiny and/or consider whether to cease filling all future orders of that drug product or all controlled substances.[107]

L. DEA CHEMICAL HANDLERS MANUAL

Cardinal Health (and others) have responded to discovery referencing the DEA's Chemical Handlers Manual and/or the 1998 Reno Report as "guidance" provided by the DEA regarding its suspicious order monitoring system for Schedule II and III controlled substances, including prescription opiates.[108] It is worth noting that these guidelines relate to "Listed Chemicals", rather than Schedule II and III controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which generally multiples a monthly base weight average per base code by a multiplier (3x)]. Notably, the Chemical Handlers Manual also mandates:

> **When a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making required reports, the transactions should not be completed until the customer is able to eliminate suspicions.**[109]

Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. Further, reliance on this threshold also does not detect orders of unusual pattern or frequency.

M. MAINTENANCE OF EFFECTIVE CONTROLS AGAINST DIVERSION OF CONTROLLED SUBSTANCES

Registrants engaged in actively distributing controlled substances should implement measures to comply with the legal and regulatory requirements. These measures should be documented as a standard operating policy for the company and be distributed to all relevant

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[106] *Id*. at CAH_MDL_PRIORPROD_DEA12_00000826, 00000837.

[107] *Id*.

[108] *See*, *e.g.*, CAH_MDL_PRIORPROD_HOUSE_0002207; CAH_MDL_PRIORPROD_DEA07_01198690.

[109] CAH_MDL_PRIORPROD_DEA07_01198690, 01198713.

employees. These standardized policies should be designed by distributors and manufacturers to take the utmost precautions to prevent diversion by maintaining the "closed system" of distribution. Included below are some key components that one would expect to see an operational system designed to maintain effective controls against diversion.

- Registrants must have a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances. The following are some of the activities utilized to establish a new customer:
    - The review to establish a new customer and begin distribution of controlled substances is a critical 1st step to ensures a potential customer has a business plan consistent with compliance to the Controlled Substances Act. The review should confirm the information provided by the potential customer is accurate. One commonly used procedure by distributors is to utilize a customer questionnaire which asks a series of questions similar to the following:
        - Past history of DEA registration to determine compliance history
        - Check of state and local licensure compliance.
        - Compliance history with state medical/pharmacy board
        - Review the business plan to determine legitimacy of the customer
        - Identify any affiliation with pain management doctors
        - Review percentage of controlled substance business
        - Identify any other distributors providing control substances
        - Review the percentage of cash payments and insurance payments
        - Review of pharmacy utilization reports
        - On-site inspection of customer
        - Internet search to determine any negative information

- 21 C.F.R. §1301.74(b) requires all manufacturers and distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. This regulation states that suspicious orders include orders of an unusual size, orders deviating substantially for a normal pattern, and orders or an unusual frequency. The regulation further states a registrant shall inform the local DEA Division Office of suspicious orders when discovered by the registrant. The regulation indicates it is the responsibility of the registrant to **design** and **operate** a suspicious order monitoring system. The design of a suspicious order system must clearly identify when the order is identified by the system. A system that establishes thresholds which are legitimate needs of a customer identified through a comprehensive "know your customer" should consider any orders exceeding that threshold as a suspicious order. The identified order should not be shipped and reported to the DEA. The subsequent shipping of that order would be after a due diligence investigation has determined the order is being shipped for legitimate use. A suspicious order system to be effective contains many components which should include, but not limited to, the following:
    - Customer Types – Customers should be placed in into customer types based on the business activity identified through the due diligence documentation.

- Scope of Practice – The system should monitor and/or restrict customers to only allow the ordering of controlled substances by schedule and type which have been identified as required for the legitimate medical needs of the practice.
- Customer Tiers/Groups – Customers who have been placed into customer types should be segregated by size in a minimum of three groups, based on the volume of their ordering history identified through the due diligence documentation.
- Drug Types – A suspicious order system to be effective should design drug types with more specificity that by drug group or drug code. Monitoring controlled substances only by the drug code or drug family is too broad and reduces the effectiveness of the system. Thresholds should also be designed for those controlled substances identified with a higher probability of being targeted for diversion.
- Thresholds – A distributor must identify the amount of controlled substances required by a customer for the legitimate operation of their business based on the registrant's knowledge of the customers business model, due diligence investigation, comparison of purchase amounts by other similar customers. Thresholds should be calculated based on the history of usage of customer for a period of at least 12 months.
- Population – The geographic distribution of controlled substances should be analyzed with relevant population information of available end users. The cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to insure it is consistent with legitimate population consumption. Customers who identify an activity of filling prescriptions from patients traveling from outside the area require a thorough due diligence type investigation including the review of dispensing records (without patient information) to confirm the legitimacy of the activity.
- Pattern of Orders – Reviewing orders to determine if there are patterns of ordering of controlled and non-controlled drugs with a comparison with relevant industry information on the most frequently prescribed drugs. If the ordering pattern deviates from established levels or what would be normal for another similarly situated customer this could indicate potential diversion.
- Pattern of Orders - Are controlled substances ordered in combinations of frequently abused drugs. As an example, purchasing the combination of oxycodone or hydrocodone products with Soma, Valium, and/or Xanax. The pattern of ordering of known highly abused controlled substances in comparison of other drugs can indicate diversion.
- Frequency of Orders – The frequency of orders for controlled substances increasing disproportionately for specific controlled substances that have been identified as being highly diverted.
- Geographic Distribution – The density of like businesses in geographic areas should be reviewed. Further, there should be a comparison of like customers in similarly situated geographic areas for deviation of volume and/or pattern of controlled substance orders. The system should identify large volume of controlled substances

consistently being received from a customer(s) in a state, county and city/township that does not have the appropriate customer base density.

- A robust and well-documented due diligence program is key for every compliance system to identify suspicious orders of controlled substances. As orders of controlled substances are identified due to factors such as size, pattern, or frequency, those orders may only be shipped if any suspicion is dispelled after adequate due diligence is conducted and it is determined that such orders are not likely to be diverted for illicit purposes. The elements and procedures involved in a due diligence compliance program for suspicious orders should be contained in a standard operation policy and should be readily available to all employees whose responsibilities touch on suspicious order monitoring. Characteristics of a robust due diligence should include the following:

    - An established procedure and criteria for setting threshold quantities.
    - The person or department who is responsible for approving threshold quantities is specifically identified.
    - A procedure for adjusting threshold quantities that requires thorough review and documentation.
    - Justification for the increase or decrease of thresholds documented by the registrant, and made after a review of factors such as the following:
        - Analysis of historical orders from the customer as well as any previous adjustments in thresholds and the justification previously provided
        - Analysis of the patient population serviced by the customer
        - Analysis of the physician population serviced by the customer
        - Analysis of the results of an adequate on-site customer review program
        - Analysis of other factors that could indicate to the registrant whether or not controlled substances are likely to be diverted for illicit purposes
    - Compliance review programs that have independent authority from other corporate entities/divisions to review thresholds as well as to approve or disapprove customers or threshold adjustments.
    - Sales role (if any) in the compliance review program must be appropriately managed.
    - On-site review includes the acquisition and review of utilization report.
    - Request for threshold changes necessitates an on-site review.
    - The person(s) is specifically identified who is responsible for reporting suspicious orders to the DEA.
    - Orders reported as suspicious that are subsequently shipped by the registrant have sufficient due diligence review being conducted and documented prior to distribution.

- The documentation of due diligence performed and the results thereof being retained
- Suspicious orders also being reported to states where applicable.
- Suspicious orders being reported as drug families and by individual drugs.
- Sufficient training and education for all involved in the distribution of controlled substances.

Almost as essential as the due diligence being conducted is that efforts made to dispel suspicions and the results thereof are adequately documented and retained. Thorough recordkeeping and documentation of the steps taken to justify flagged orders are necessary not only to explain why decisions were made in any particular instance, but also to inform future decisions regarding flagged orders. One important aspect of every due diligence review should always be an examination of the historical transactions of the customer who placed the flagged order. Such an examination is necessary to evaluate trends over time and to inform decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels. For purposes of conducting a historical review of a customer when evaluating a flagged order, if prior due diligence investigations are not adequately documented and retained, they may as well have not occurred at all.

As explained above, the goal of suspicious order monitoring is to ensure that bulk orders of controlled substances are being shipped for legitimate purposes rather than being diverted for illicit purposes. A suspicious order monitoring system has a self-policing aspect with the twin aims of both stopping the shipment of orders at risk of diversion and investigating those who have placed orders that are identified as suspicious. Not shipping a suspicious order is only part of the equation. The other parts are investigating the buyer and the circumstances surrounding the order and, if necessary, reporting the suspicious order to the DEA. Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk. The suspicious order monitoring system failures described above directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances. These orders never should have shipped until after the suspicion of diversion was dispelled.

III. Identifying Suspicious Orders Distributed in CT1

I have described in this report the ways in which distributor and manufacturer defendants' inadequate response to their statutory and regulatory requirements to maintain effective controls related to the sales of prescription opioids would potentially cause the diversion of these pills for non-medical use. I have reviewed five suspicious order methodologies, some of which were

utilized by one or more of the defendants. These methodologies are identified in the McCann Report as "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," and "Maximum Daily Dosage Units." The purpose of each system was to identify suspicious orders that should not be shipped unless the distributors' due diligence eliminated the suspicion of diversion. Each method would have identified a significant volume of orders of opiates as shown in the tables below.[110]

A. Methodology: Maximum Monthly, Trailing 6 Month Threshold

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 46)	[redacted]	
Cardinal (p. 91)		
McKesson Corporation (p. 136)		
CVS (p. 181)		
Walgreens (p. 236)		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug (p. 676)	[redacted]	
Cardinal (p. 721)		
McKesson Corporation (p. 766)		
CVS (p. 811)		
Walgreens (p. 236)		

[110] I utilized these Defendants: Cardinal Health, AmerisourceBergen Drug, McKesson, Walgreens, and CVS as they constitute a significant majority of the opioid pills delivered into CT1 according to the data described in the Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, pp. 3775 and 3845.

B. Methodology: 2x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[111]	[redacted]	
Cardinal[112]		
McKesson Corporation[113]		
CVS[114]		
Walgreens[115]		

Summit County: 1996-2018

Distributor
AmerisourceBergen Drug[116]
Cardinal[117]
McKesson Corporation[118]
CVS[119]
Walgreens[120]

[111] *Id.* at 55.

[112] *Id.* at 100.

[113] *Id.* at 145.

[114] *Id.* at 190.

[115] *Id.* at 235.

[116] *Id.* at 685.

[117] *Id.* at 730.

[118] *Id.* at 775.

[119] *Id.* at 20.

[120] *Id.* at 865.

C. Methodology: Extraordinary Order Method - 3x Trailing 12 Month Average

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[121]	[redacted]	
Cardinal[122]		
McKesson Corporation[123]		
CVS[124]		
Walgreens[125]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[126]	[redacted]	
Cardinal[127]		
McKesson Corporation[128]		
CVS[129]		

[121] *Id.* at 64.

[122] *Id.* at 109.

[123] *Id.* at 154.

[124] *Id.* at 199.

[125] *Id.* at 244.

[126] *Id.* at 694.

[127] *Id.* at 739.

[128] *Id.* at 784.

[129] *Id.* at 829.

Walgreens[130]	[redacted]

D. Methodology: Maximum 8,000 Dosage Units Monthly

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[131]	[redacted]	
Cardinal[132]		
McKesson Corporation[133]		
CVS[134]		
Walgreens[135]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[136]	[redacted]	
Cardinal[137]		
McKesson Corporation[138]		

[130] *Id.* at 874.

[131] *Id.* at 73.

[132] *Id.* at 118.

[133] *Id.* at 163.

[134] *Id.* at 208.

[135] *Id.* at 253.

[136] *Id.* at 703.

[137] *Id.* at 748.

[138] *Id.* at 793.

CVS[139]	[redacted]
Walgreens[140]	

E. Methodology: Maximum Daily Dosage Units

Cuyahoga County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[141]	[redacted]	
Cardinal[142]		
McKesson Corporation[143]		
CVS[144]		
Walgreens[145]		

Summit County: 1996-2018

Distributor	Flagged Orders of Oxycodone (Dosage Units)	Flagged Orders of Hydrocodone (Dosage Units)
AmerisourceBergen Drug[146]	[redacted]	
Cardinal[147]		

[139] *Id.* at 838.

[140] *Id.* at 883.

[141] *Id.* at 82.

[142] *Id.* at 127.

[143] *Id.* at 172.

[144] *Id.* at 217.

[145] *Id.* at 262.

[146] *Id.* at 712.

[147] *Id.* at 757.

McKesson Corporation[148]	[redacted]
CVS[149]	
Walgreens[150]	

I have been asked to identify the number of opioid pills that entered Cuyahoga and Summit Counties unlawfully. This is an impossible task due to the defendants' failure to comply with their Federal statutory and regulatory requirements.[151] However, it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size.[152] *See* Methodology A above. Pursuant to *Masters,* "as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence" *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.

Based on my education, background, and experience, as well as my review of relevant documents, the absence of adequate distributor due diligence and failure to respond to indicators of suspicious orders as described in this report constitutes the Defendants' failures to comply with the requirements of the Controlled Substances Act. It is further my opinion that this misconduct led to the excess quantity of opiate pills flooding the illicit market in CT1 jurisdictions.

IV. REGISTRANT SUSPICIOUS ORDER MONITORING SYSTEMS (SOMS)

I have been asked to review the documents produced in this litigation to determine whether the distributors complied with the statutory and regulatory duties outlined above. In this process I have reviewed numerous documents and depositions for each of the enumerated Defendants. Based on my review it is my opinion to a reasonable degree of professional certainty that each of the distributors failed to comply with their statutory and regulatory duty to maintain effective controls to prevent diversion and to design and operate a system to identify and report suspicious orders.

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[148] *Id*. at 802.

[149] *Id*. at 847.

[150] *Id*. at 892.

[151] This includes, but is not limited to, the requirement of the defendants to maintain effective controls against diversion, the reporting requirement, and the not shipping requirement. The detail of some of these failures is set out more completely below in the distributor and manufacturer specific sections of this report.

[152] This approach does not take into consideration unusual pattern or frequency.

A. Cardinal Health

Distribution Center: Wheeling, WV

DEA Registrant Number: RO0153609

Transactional Data Disclosed:

Date range: 01/01/1996 through 05/01/2018[153]

Volume: Cuyahoga County

Cuyahoga[154]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

Summit County

Summit[155]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

1. Court ordered SOMS Discovery Disclosure:

- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' First Combined Discovery Requests* (July 31, 2018)
- *Cardinal Health, Inc.'s First Supplemental Objections and Responses to Plaintiffs' First Combined Discovery Requests* (November 30, 2018)
- *Cardinal Health, Inc.'s Second Supplemental Objections and Responses To Plaintiffs' First Combined Discovery Requests* (January 22, 2019)
- *Cardinal Health, Inc.'s Third Supplemental Objections and Responses To Plaintiffs' First Combined Discovery Requests* (March 4, 2019)
- *Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' First Set of Requests for Production of Documents* (May 29, 2018)
- *Cardinal Health, Inc.'s Objections and Supplemental Responses to Plaintiffs' First Set of Interrogatories* (November 30, 2018)
- *Cardinal Health, Inc.'s Objections and Second Supplemental Responses to Plaintiffs' First Set of Interrogatories* (March 4, 2019)
- *Cardinal Health, Inc.'s Revised Objections and Third Supplemental Responses to Plaintiffs' First Set of Interrogatories* (March 25, 2019)
- *30(b)(6) Deposition of Cardinal Health (Jennifer Norris)* (August 7, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 1* (September 11, 2018)

[153] CAH_MDL2804_00000012, CAH_MDL2804_00000014, CAH_MDL2804_00135241, and CAH_MDL2804_00617320.

[154] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 91.

[155] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 721.

- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics (O), 9-11* (October 18, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 2* (October 25, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 3-5* (November 9, 2018)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 13, 15-21* (November 14, 2018)
- *Cardinal Health's Supplemental Written Response to Plaintiffs' 30(b)(6) Topic (a)* (January 24, 2019)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topics 16-18* (January 24, 2019)
- *Cardinal Health's Revised and Supplemental Written Response to Plaintiffs' 30(b)(6) Topic (a)* (March 4, 2019)
- *Cardinal Health's Written Response to Plaintiffs' 30(b)(6) Topic 14* (March 4, 2019)

2. SOMS Corporate Policy Disclosed:

Cardinal Health DEA Compliance Manual (April 5, 2000)[156]

This system that Cardinal used from April of 2000 till sometime in late 2007/early 2008 had two operational aspects. First, Cardinal Health utilized the Ingredient Limit Reports, which were generated as a retrospective review of the prior month's distribution data based on a formula that was applied on a monthly basis. A hard copy was then mailed to the local DEA office. According to Mr. Reardon, Vice President Quality and Regulatory Affairs from 2005 to 2007 and a Director in regulatory prior to 2000, this system was utilized by Cardinal as far back as the early 1990's. *See* Deposition of Steve Reardon, November 30, 2018 at 410: 10 to 411: 11 and 429: 3-10. The second part of this system was to have cage/vault employees looking for suspicious orders based on the "Excessive Purchases Schedule II" and "Excessive Purchases Schedule III, IV, V" charts.[157] If Cardinal's pickers and checkers spotted an excessive order they were to notify the local DEA office prior to shipment of the order if possible and place a copy of these orders in the distribution center's suspicious order file along with a Regulatory Agency Contract Form (Form #1) noting any specific instructions from the DEA.[158]

Cardinal SOM Program (12/01/2007 through 12/22/2008) [159]

The next step in the evolution of Cardinal's SOM Programs is unclear. According to document CAH_MDL2804_01522227 Cardinal's policies change on this date to incorporate threshold and a know your customer (KYC) system. However according to sworn testimony for Cardinal via its 30(b) designee Jennifer Norris, Cardinal does not know what changes it made

[156] CAH_MDL_PRIORPROD_DEA07_01383895, 01383939-01384041.

[157] *See* CAH_MDL_PRIORPROD_DEA07_01383136, 01384160-01384161.

[158] CAH_MDL_PRIORPROD_DEA07_01383895, 01383940 and 01384080.

[159] CAH_MDL2804_01522227

within its SOM systems from September 2006 through at least late 2007. *See Norris* Deposition at page 292.

Cardinal SOM Program (12/22/2008 forward)[160]

In 2008 Cardinal implemented several Standard Operating Procedures (SOP) related to anti-diversion. This system also had two primary components. The first component was threshold utilization. This included setting a specific threshold (based on dosage unit) for each customer for each controlled drug base code or drug family and if the customer exceeded the allotted threshold the order was to be held and not shipped. The second component to this system was "Know Your Customer" (KYC) and it obligated Cardinal to know who they were dealing with. The threshold process and KYC are discussed in more detail in other portions of my report.

3. Enforcement Actions

a) On December 26, 2006, Cardinal entered into an Assurance of Discontinuance Pursuant to Executive Law §63(15) with the NY AG related to its failures to prevent and monitor price diversion and closed door pharmacies;[161]

b) On September 18, 2007, the DEA issued a *Warrant for Inspection* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;[162]

c) On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;[163]

d) On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;[164]

e) On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution

[160] CAH_MDL_PRIORPROD_AG_0004208, CAH_MDL_PRIORPROD_AG_0000323, CAH_MDL_PRIORPROD_AG_0000344, CAH_MDL_PRIORPROD_AG_0000101, CAH_MDL_PRIORPROD_DEA12_00014535, 00014536; CAH_MDL_PRIORPROD_AG_0000013

[161] CAH_MDL_PRIORPROD_DEA07_00833777.

[162] CAH_MDL2804_02110916, 02110918-02110923.

[163] CAH_MDL2804_00641449, 00641465.

[164] CAH_MDL2804_00641449, 00641469.

Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;[165]

f) On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;[166]

g) On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at all 27 of Cardinal's distribution centers nationwide;[167]

h) On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;[168] and

i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.[169]

4. Suspicious Orders Reported In CT1 Jurisdictions

	Pre-Shipment Reporting	Post-Shipment Reporting
1996	[redacted]	
1997		
1998		
1999		
2000		
2001		
2002		
2003		
2004		
2005		[redacted]

[165] CAH_MDL2804_00641449, 00641474.

[166] CAH_MDL2804_00641449, 00641479

[167] CAH_MDL2804_00641449.

[168] CAH_MDL2804_02465982.

[169] CAH_MDL2804_0005778.

2006		[redacted]		[redacted]
2007				
2008				
2009				
2010				
2011				
2012				
2013				
2014				
2015				
2016				
2017				
2018				

5. Due Diligence Conducted

Due Diligence is one of the core components of any SOMS and must be fully integrated if the SOMS is going to work adequately. The basic premise for due diligence is that a registrant must know who they are dealing with when distributing controlled substances (potentially dangerous drugs) into surrounding communities. Cardinal's due diligence system has evolved over time and while it has made general improvements in theory the overall application of the system does not meet its regulatory requirement to maintain effective controls against diversion.

Cardinal's due diligence prior to 2006 is very limited, and it is difficult to discern exactly what due diligence was conducted by Cardinal prior to 2006. Cardinal cited to a defined list of documents in its Second Supplemental Combined Discovery Responses as the production related to due diligence conducted on the Cuyahoga County and Summit County customers.[170] It appears that prior to 2006 Cardinal's customer due diligence was limited in fashion. The best I can tell it appears that Cardinal solely sought to ensure compliance with 21 CFR 1301.74(a) which reads in pertinent part:

> Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substance registration agency, if any, to determine that the person is registered to possess the controlled substance.

[170] *See* Cardinal Second Supplemental Combined Discovery Responses, citing CAH_MDL2804_00000015 – 00001851, CAH_MDL2804_00094067–00094604, CAH_MDL2804_00135242, CAH_MDL2804_00619125, CAH_MDL2804_01287246–01287525, CAH_MDL2804_02098561, CAH_MDL2804_02101808, and CAH_MDL2804_02879401–02879958

While such due diligence is a first step in the process it does not meet the required level of compliance to ensure a sufficient level of maintenance of effective control by which a registrant should operate.

In 2005 it appears that the NY AG began an investigation of Cardinal related to the distribution of its products.[171] This matter involves, amongst other allegations, price diversion with closed door pharmacies that engaged in contract pricing. This matter resolved in December of 2006 with the entry of an Assurance of Discontinuance. This appears to have caused Cardinal to create its first customer screening and monitoring process at least as it applies to "closed-door pharmacy customers at contract pricing."[172] This policy is very limited in its application to "closed-door pharmacy customers at contract pricing" and there was no indication that a like policy was enacted for Cardinal's remaining customers. The main function of this policy as it relates to due diligence was to require a "Contract Pricing Declaration" and a "Site Visit Form." This process did not constitute adequate due diligence for these customers. Additionally, it appears that these forms were not utilized prior to 2006, confirming the lack of due diligence even for closed-door pharmacies prior to that date.[173]

In 2007/2008 when Cardinal was being investigated by the DEA and received immediate suspension orders for three of its distribution centers, I see the next significant change in the due diligence process in place at Cardinal. This is first demonstrated in a training manual that is prepared by Eric Brantley (at least the manual bears his name) and dated October 2007 and is titled Know Your Customer Program: Retail Pharmacy Questionnaire Training.[174] There is also a related document that is an email from Gary Cacciatore sent on December 9, 2007 indicating this training is being rolled out to the "independent retail sales team" to be completed by December 19, 2007.[175] For this time frame up until 2012 there appears to be some due diligence/know your customer functions occurring in Cuyahoga County and Summit County for retail independent pharmacies/drug stores but not to the extent I have outlined above.[176]

During this same time, 2007/2008 to 2012, there seems to be very little in implementation of actual policies related to know your customer/due diligence.[177] Cardinal Health provided almost preferential treatment to its chain pharmacies/national accounts as compared to their retail independent customers. Cardinal Health's policies did not reflect this almost preferential treatment. Cardinal admittedly did not conduct the same due diligence on its chain

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[171] *See* CAH_MDL_PRIORPROD_DEA07_00833777.

[172] *See* CAH_MDL_PRIORPROD_DEA07_00871842.

[173] *See* CAH_MDL_PRIORPROD_DEA07_00008894.

[174] *See* CAH_MDL_PRIORPROD_DEA07_02738896.

[175] *See* CAH_MDL_PRIORPROD_DEA07_02738893.

[176] *See* Section II. (M.).

[177] *See*, *e.g.*, Due Diligence files produced by Cardinal Health for customers in the City of Cleveland, Cuyahoga County, and Summit County, CAH_MDL2804_00000015 –00001851, CAH_MDL2804_00094067–00094604.

customers during this time period.[178] This practice is not acceptable for maintaining effective controls against diversion and is a breach of Cardinal's obligation as a registrant. As indicated above, there was clearly some due diligence being conducted, some of which occurred in the way of on-site investigations, however, according to the Special Demand Committee Report of Cardinal's Board of Directors, those investigations were not being reviewed properly.[179] These requirements are not intended to be an act in futility but are a useful and necessary tool in meeting the registrant's regulatory requirements.

There are several examples of this lack of due diligence/KYC occurring in Cuyahoga County and Summit County over this span of years. These examples are based on documents identified in the Second Supplemental Combined Discovery Responses, which identify the due diligence files for Cuyahoga County and Summit County. Looking at New Choice Pharmacy, which is located in Summit County, it appears that it initially became a customer of Cardinal's in approximately May 2004 and remained a customer until approximately September 2015. During this timeframe New Choice went through three changes of DEA registration numbers (FN1432854, BC8680399, and BN8680399) with no real explanation for this in the produced due diligence file.[180] There could have been several reasons for this change, such as a change of ownership or change is business model. The distribution of oxycodone to New Choice showed a pattern of growth from [redacted] dosage units of oxycodone in May 2004 to over [redacted] dosage units in August 2007 and there appears to be no due diligence until January 2008.[181] The documents within this due diligence file fail to recognize risk factors that are apparent while Cardinal continued to increase the threshold for oxycodone, and eventually on March 7, 2008, the threshold increased to [redacted] oxycodone dosage units per month.[182] While New Choice was located in a medical complex, and for a time was owned by a hospital group, it did not service the hospital and instead actually serviced a pain clinic. Its controlled substances sales constituted [redacted] of total sales in the early part of 2008. The due diligence that is contained in Cardinal's files is not sufficient to justify this large amount of oxycodone and does not meet Cardinal's regulatory requirement.[183]

The next example is a chain pharmacy known as CVS #3322 (DEA# AR7531418), which appears to have been a customer of Cardinal's from 2000 to at least May 2018. CVS #3322's purchases of oxycodone increased over time from [redacted] for the month of February 2000 to a high of [redacted] for October 2012. There is a due diligence file produced by Cardinal for CVS 3322, but

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[178] *See* Declaration of Michael A. Mone, CAH_MDL_PRIORPROD_DEA12_00014053 at page 13.

[179] *See Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36.

[180] *See* New Choice Pharmacy Due Diligence file, CAH_MDL2804_00000605-00000618, CAH_MDL2804_00001518-00001540.

[181] *See id*.; *see also* Expert Report of Craig J. McCann, Ph.D, CFA, App. 9, pp. 1424, 1524, and 1536.

[182] *See* CAH_MDL2804_00619126 and CAH_MDL2804_02098561.

[183] *See* New Choice Pharmacy Due Diligence file, CAH_MDL2804_00000605-00000618, CAH_MDL2804_00001518-00001540.

there is no documented due diligence prior to January 24, 2014.[184] The diligence that is noted on this date is a "surveillance site visit report," which according to Mr. Forst is completely different than an on-site investigation.[185] Again, this level of due diligence is not sufficient to meet Cardinal's regulatory obligations and, as set out above, relying on the chain to conduct their own due diligence does not meet regulatory requirements.

6. Opinions Related to Cardinal Health

1. Cardinal Health failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].

The bar graphs identified as Figures 3-14 in Schedule II to this report demonstrate a clear increase of distribution of prescription opioids into Cuyahoga County and Summit County by dose, base weight and MME. In my opinion the massive increase in prescription opioids without sufficient due diligence documented is indicative of a failure to maintain effective control.

2. Cardinal Health failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).

a. Policy Period #1 (1996 to 2008):

i. **Ingredient Limit Reports**

Cardinal Health claims its system from 1996 to 2008 was premised upon "guidance" from the 1998 DEA Reno Report.[186] The record does not reveal any documentation which supports this contention.[187] Moreover, the Reno Report provides guidance on monitoring monthly orders of chemicals used to make illicit methamphetamine. The Reno Report, referencing the Chemical Handlers Manual, advises a distributor to set an "ingredient limit" as a tool to detect monthly orders of ***extraordinary*** size. This limit is determined by calculating a monthly average for similarly situated customers and multiplying by a factor of three (3). Monthly orders in excess of this limit are deemed "extraordinary" and must be reported.

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[184] *See* CVS #3322 Due Diligence file, CAH_MDL2804_00000204-00000219.

[185] *See* Depo. of Stephen Forst, 30:4-33:19.

[186] Cardinal Health's Supplemental Response to Plaintiffs' First Combined Discovery Request No. 3 (November 30, 2018); Deposition of Jennifer Norris (30(b) Designee for Cardinal Health), 134:16-23.

[187] *See* Deposition of Jennifer Norris (30(b) Designee for Cardinal Health); Cardinal Health's original and First, Second, and Third Supplemental Responses to Plaintiffs' Frist Combined Discovery Request; Cardinal Health's Written Original and Supplemental Responses to Plaintiffs' First Notice of 30(b) Deposition, Topic (a). Furthermore, while there is not necessarily evidence that the "guidance" Cardinal allegedly received was communicated by a DEA field agent, to the extent it was, pursuant to the reasoning in *Novelty Distributors, Inc.,* 73 Fed. Reg. 52,689, n. 53 (Drug Enf't Admin. September 3, 2008), Cardinal's reliance on an agent's "erroneous understanding of the law and regulations" would have been misplaced..

Cardinal Health used this methodology to monitor controlled substances but used a factor of four (4) to identify ***unusual*** monthly orders. This design is insufficient to meet the security requirement because: (a) it fails to identify suspicious orders before shipment; (b) it uses after-the-fact reporting of suspicious orders; (c) it ships suspicious orders; and (d) it uses a 4x factor which is in excess of the factor recommended by the Reno Report to detect orders of ***extraordinary*** size. Cardinal Health knew or should have known that such a system, by itself, is woefully insufficient to meet its obligations under federal law.

If Cardinal Health designed its system in accordance with the DEA Diversion Investigators Manual (1996), a copy of which it had in its possession since at least 2003, it would have identified a serious problem in Cuyahoga County and Summit County. The Manual states:

> ***Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824. Suspicious orders include those which are in excess of legitimate medical use or exhibit characteristics leading to possible diversion such as: orders of unusual size, unusual frequency, or those deviating substantially from a normal pattern. The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area. If the customer exceeds this threshold, the request should be viewed as suspicious. This activity, over extended periods of time, would lead a reasonable person to believe that controlled substances possibly are being diverted.***[188]

Cardinal Health did not retain the algorithm nor the formula used to calculate the average purchase of controlled substances by the distribution center servicing Cuyahoga County and Summit County.[189] However, Cardinal Health produced Ingredient Limit Reports from its Wheeling Distribution Center from which the following "ingredient limits" of oxycodone and hydrocodone can be derived:

Bates Range	**Date**	**Limit for 9143**	**Limit for 9193**
CAH_MDL_PRIORPROD_DEA07_01465435 – 01465712 (*see* CAH_MDL_PRIORPROD_DEA07_01465497)	August 2005	[redacted]	
CAH_MDL_PRIORPROD_DEA07_01713984 – 01714260	September 2005		

[188] *See* CAH_MDL2804_02203353.

[189] *See* Special Master Cohen Discovery Hearing Transcript of January 25, 2019, pp. 60-67.

(*see* CAH_MDL_PRIORPROD_DEA07_01714045)		
CAH_MDL_PRIORPROD_DEA07_01676164 – 01676385 (*see* CAH_MDL_PRIORPROD_DEA07_01676206)	October 2005	[redacted]
CAH_MDL_PRIORPROD_DEA07_01640601 – 01640859 (*see* CAH_MDL_PRIORPROD_DEA07_01640661)	November 2005	
CAH_MDL_PRIORPROD_DEA07_01698986 – 01699238 (*see* CAH_MDL_PRIORPROD_DEA07_01699031)	December 2005	
CAH_MDL_PRIORPROD_DEA07_01554009 – 01554254 (*see* CAH_MDL_PRIORPROD_DEA07_01554060)	January 2006	
CAH_MDL_PRIORPROD_DEA07_01538085 – 01538299 (*see* CAH_MDL_PRIORPROD_DEA07_01538126)	February 2006	
CAH_MDL_PRIORPROD_DEA07_01611135 – 01611464 (*see* CAH_MDL_PRIORPROD_DEA07_01611192)	March 2006	
CAH_MDL_PRIORPROD_DEA07_01641502 – 01641682 (*see* CAH_MDL_PRIORPROD_DEA07_01641540)	April 2006	
CAH_MDL_PRIORPROD_DEA07_01788800 – 01789058 (*see* CAH_MDL_PRIORPROD_DEA07_01788850)	May 2006	
CAH_MDL_PRIORPROD_DEA07_01590839 – 01591156 (*see* CAH_MDL_PRIORPROD_DEA07_01590908)	June 2006	
CAH_MDL_PRIORPROD_DEA07_01573797 – 01574019	July 2006	

(*see* CAH_MDL_PRIORPROD_DEA07_01573850)		
CAH_MDL_PRIORPROD_DEA07_01475709 – 01475962 (*see* CAH_MDL_PRIORPROD_DEA07_01475761)	August 2006	[redacted]
CAH_MDL_PRIORPROD_DEA07_01723108 – 01723339 (*see* CAH_MDL_PRIORPROD_DEA07_01723159)	September 2006	
CAH_MDL_PRIORPROD_DEA07_01685103 – 01685339 (*see* CAH_MDL_PRIORPROD_DEA07_01685159)	October 2006	
CAH_MDL_PRIORPROD_DEA07_01650463 – 01650717 (see CAH_MDL_PRIORPROD_DEA07_01650518)	November 2006	
CAH_MDL_PRIORPROD_DEA07_01515965 – 01516204 (*see* CAH_MDL_PRIORPROD_DEA07_01516022)	December 2006	
CAH_MDL_PRIORPROD_DEA07_01563313 – 01563602 (*see* CAH_MDL_PRIORPROD_DEA07_01563374)	January 2007	
CAH_MDL_PRIORPROD_DEA07_01546013 – 01546207 (*see* CAH_MDL_PRIORPROD_DEA07_01546054)	February 2007	
CAH_MDL_PRIORPROD_DEA07_01620843 – 01621127 (*see* CAH_MDL_PRIORPROD_DEA07_01620900)	March 2007	
CAH_MDL_PRIORPROD_DEA07_01457031 – 01457282 (*see* CAH_MDL_PRIORPROD_DEA07_01457086)	April 2007	
CAH_MDL_PRIORPROD_DEA07_01747160 – 01747495	May 2007	

(*see* CAH_MDL_PRIORPROD_DEA07_01747222)		
CAH_MDL_PRIORPROD_DEA07_01601686 – 01601970 (*see* CAH_MDL_PRIORPROD_DEA07_01601749)	June 2007	[redacted]
CAH_MDL_PRIORPROD_DEA07_01544958 – 01545544 (*see* CAH_MDL_PRIORPROD_DEA07_01545069)	July 2007	
CAH_MDL_PRIORPROD_DEA07_01488350 – 01488972 (*see* CAH_MDL_PRIORPROD_DEA07_01488469)	August 2007	
CAH_MDL_PRIORPROD_DEA07_01732427 – 01732872 (*see* CAH_MDL_PRIORPROD_DEA07_01732511)	September 2007	
CAH_MDL_PRIORPROD_DEA07_01696166 – 01696738 (*see* CAH_MDL_PRIORPROD_DEA07_01696272)	October 2007	
CAH_MDL_PRIORPROD_DEA07_01660982 – 01661449 (*see* CAH_MDL_PRIORPROD_DEA07_01661075)	November 2007	
CAH_MDL_PRIORPROD_DEA07_01525200 – 01525688 (*see* CAH_MDL_PRIORPROD_DEA07_0155294)	December 2007	
CAH_MDL2804_00689780 – 00690378 (*see* CAH_MDL2804_00689879)	April 2008	

Additionally, by reviewing this chart it exemplifies some of the concerns I have with Cardinal Health's SOMS. This ILR information is all from Cardinal Health's Wheeling distribution center and we can see that for this geographic area the limiter amount for oxycodone is decreasing from October 2005 through March 2007 from 140.26240 down to 104.40680. Then in April of 2007 the limiter begins to increase until April 2008 (did not have ILR's for January, February, and March of 2008), climbing from 104.82816 up to 211.60004, more than doubling the amount of oxycodone in a year's time. It is my understanding that this distribution center provides

distribution services to Ohio, West Virginia, and parts of Pennsylvania.[190] This drastic increase should have triggered an investigation to ensure the legitimacy of the orders placed by the customers for oxycodone.

ii. **Excessive Orders**

Cardinal Health's system (early 1990's-2008)[191] was also designed to identify "individual orders that appear to be excessive" on a daily basis and notify the DEA, if possible, before the order is shipped. Excessive orders are defined by the following dosage limits:

Hydrocodone	800 Tabs/Caps
Oxycodone / Acet (Tylox, Roxilox, Roxicet. Percocet. Endocet)	1200 Tabs/Caps
Oxycodone/Asa (Percodan, Endodan, Roxiprin)	500 Tabs
Oxycodone (Oxycontin, Roxicodone)	600 Tabs[192]

During this timeframe Steve Reardon, Vice President Quality and Regulatory Affairs, was over the anti-diversion department at Cardinal Health. Mr. Reardon testified that this "Excessive Order" system was expected to be implemented the same across the whole company and implemented uniformly.[193] According to Mr. Reardon, Cardinal Health's policy was for any order that exceeded these "Excessive Order" postings in the cage to be reported to the DEA as a suspicious order **prior to shipment**.[194]

I asked SLCG to determine how many daily orders exceeded the daily limit set by Cardinal Health between 1996 to 2018 which resulted in the following:

Cuyahoga County:[195] [redacted][196] orders of oxycodone ([redacted] of all oxycodone orders) exceeded the daily limit. These orders included [redacted] dosage units of oxycodone.

[190] *See* Deposition of Craig Baranski, p. 82-83.

[191] *See* Deposition of Steve Reardon, p. 429.

[192] CAH_MDL_PRIORPROD_DEA07_01383136, 01383401.

[193] *See* Reardon at 455 to 456.

[194] *See* Reardon at 453 to 456.

[195] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 127.

[196] *Id*. at Table 32.

[redacted][197] orders of hydrocodone ([redacted] of all hydrocodone orders) exceeded the daily limit. These orders included [redacted] dosage units of hydrocodone.

Summit County:[198] [redacted][199] orders of oxycodone ([redacted] of all oxycodone orders) exceeded the daily limit. These orders included [redacted] dosage units of oxycodone.

[redacted][200] orders of hydrocodone ([redacted] of all hydrocodone orders) exceeded the daily limit. These orders included [redacted] dosage units of hydrocodone.

I have not been able to locate any reports related to orders in excess of the daily limit for the Wheeling distribution center produced in this matter. Furthermore, evidence in the record indicates that Cardinal Health employees instructed its personnel to ignore the daily limits. Cardinal Health's employee, Dave Strizzi, claims that these excess "charts" are for guidance and that orders should not be cut but that staff should "record the orders that exceed these limits for possible reporting to the DEA."[201] This is completely inconsistent with the way Cardinal Health's policy reads as well as the way Mr. Reardon explained it. Even more concerning, on November 1, 2006, Rafael Varela, one of Cardinal Health's QA & Compliance Managers, wrote "the Vault Keyers were, until today, overriding the limiters for the vault items in the system… This is not supposed to happen without authorization."[202]

Even if the daily limit system was designed properly as a tool to identify suspicious orders, it appears there is no evidence the system was sufficiently "operated." This concern was clear even to the employees at Cardinal Health. On December 5, 2007, just after the license suspension of Cardinal Health's Auburn distribution center, Bob Kurtz sent a follow-up email to Rafael Varela, one of Cardinal Health's Compliance and QA Managers, and explained the following related to Cardinal's "picker and checker" system:

> The manual process we perform now with the discovery of suspected excessive purchases being left up to the keyer notifying myself, or a picker/double checker/QCer questioning an amount being processed seems to **leave ample opportunity for failure**. A system generated "flag" would be a more complete or thorough method of determining spikes or excessive quantities than what we are currently performing.

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[197] *Id.*
[198] *Id.* at p. 757.
[199] *Id.* at Table. 33.
[200] *Id.*
[201] *See* CAH_MDL PRIORPROD_ DEA07_00319489.
[202] *See* CAH_MDL PRIORPROD_ DEA07_01052516.

> As you know, I've investigated many accounts, tracked their ordering history, and reached out for guidance and directions. But without "someone" bringing a suspected "excessive quantity" order to our attention, **many, many more could be going out the door under our noses**. **I wonder could a similar situation happen in Lakeland and management be questioned "why wasn't this discovered?"**[203]

In my opinion, this represents a breach of the security requirement as it applies to Cardinal Health.

This is all consistent with the testimony of Mark Hartman, who took over the regulatory department in December 2007, as the Senior Vice President of Supply Chain Integrity.[204] According to Mr. Hartman as well as a power point presentation that he prepared, Cardinal Health had leaks in their supply chain.[205] This is during the same time that Cardinal was addressing three Immediate Suspension Orders and one Order to Show Cause across four of its distribution centers related to Cardinal Health's failure to maintain effective controls against diversion.[206] Specifically, Cardinal Health was alleged to have been failing to comply with its regulatory duties and distributing excess oxycodone, which is consistent with my opinions for Policy Period #1.

Even Cardinal Health's counsel recognized that Cardinal Health did not have a sufficient SOMS to properly detect all suspicious orders during this timeframe.[207] Prior to and during portions of 2008, Cardinal Health was still delivering not only controlled substances, but oxycodone in particular, after being specifically told that such an action would be illegal.[208] Further, a spreadsheet produced by Cardinal describes a number of pharmacies, including some in CT1 jurisdictions, that Cardinal cut off prior to 2008 and the underlying reasons for termination.[209] This document shows that Cardinal serviced pharmacies whose purchase histories, ratio of purchases of controlled to non-controlled substances, ratio of cash for purchases of controlled substances, total volume of certain controlled substances (hydrocodone, oxycodone), and other factors indicated potential diversion. Had Cardinal investigated these pharmacies sooner, as it should have, Cardinal would have been aware of this activity.

b. Policy Period #2 (2008 to 2012):

i. **Thresholds**

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[203] *See* CAH_MDL_PRIORPROD_DEA07_00135433 (emphasis added).

[204] *See* Deposition of Mark Hartman at 17:11-16.

[205] *See id*. 236: 5-13, *see also* Hartman Depo. Exhibit 13.

[206] CAH_MDL2804_00641449.

[207] *See* CAH_MDL_PRIORPROD_DEA07_00968964 ("[H]ere, you have an Inet Pharmacy, the account is open, and Cardinal does not yet have a system for detecting all suspicious orders.").

[208] *Id*.; *see also*, Schedule IV, distributions to Ross Westbank (2006-2014).

[209] CAH_MDL2804_00664969.

After the DEA instituted an enforcement action against Cardinal Health, it began implementing a different SOM system in 2008. Cardinal Health claims that this revised system focused on a dual approach. The first approach used in this system required the creation of a Threshold for each customer and that the Threshold be specific for each base code. The Threshold was designed to operate as a stop on any shipment which exceeded the predetermined Threshold.[210] The Second step in this process required Cardinal Health to be familiar with its customers (Know Your Customers). The record does not support that Cardinal Health complied with their own thresholds. To the contrary, Cardinal Health continued to ship orders that exceeded their own Thresholds without complying with their KYC requirements or conducting sufficient due diligence before shipping suspicious orders.

Cardinal Health's approach to setting these Thresholds for its customers, as with the ILR's, was fatally flawed. Cardinal Health's Threshold system required it to determine the 12 month average for its customers, for each base code based on type and size of customer, and multiply that average by a multiple of 3 for schedule II's and a multiple of 5 for schedule III's.[211] This too is insufficient under the security requirement because: (a) it premises setting a threshold limit in the middle of a national opioid epidemic;[212] and (b) Cardinal Health relies on the Reno Report[213] using a 3x and 5x multiple respectively, which, again, is recommended only to apply to extraordinary size of controlled substances containing List 1 chemicals, and not to Schedule II and Schedule III controlled substances which do not contain List I chemicals.[214]

Cardinal Health's productions demonstrate that it regularly ignored the thresholds it had set for its customers. The DEA found that following the 2008 settlement with the DEA, Cardinal failed to report any suspicious orders of oxycodone products for pharmacies in Maryland between 2008 and October 1, 2011.[215] During this time, the DEA found that Cardinal Health increased thresholds for these Maryland pharmacies despite evidence indicating potential diversion.[216] This fact was also part of the 2012 DEA enforcement action based on Cardinal Health's Florida conduct. This appears to be a systemic problem that was occurring throughout Cardinal Health's nationwide operations. Documents provided by Cardinal Health related to the *Holder v. Cardinal Health* litigation demonstrates this point. The following are examples of the number of times customers were permitted to exceed their predetermined thresholds:

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[210] *See Deposition of Shirlene Justus*, July 13, 2018 at 86:14 to 88:6.

[211] CAH_MDL_PRIORPROD_AG_0000013.

[212] *See* Deposition of Mark Hartman, 286:5-11.

[213] *See* Deposition of Jennifer Norris (Cardinal Health 30(b) Designee), 134:16-23 ("An ingredient limit report is the report that was required pursuant to the 1998 DEA report to, I believe, the Attorney General. It included the algorithm for certain pharmaceuticals, and we on a monthly basis provided the report of the customers who had exceeded the designated amount that you achieve pursuant to doing the algorithm, the math problem.").

[214] *See* Deposition of Steve Reardon, 432:8-433:3.

[215] CAH_MDL2804_025097322, 02509741.

[216] *Id*. at 02509756, 02509758, 02509764, 02509780

- CVS 219 allowed to exceed its threshold 14 out of 16 months.
- Gulf Coast allowed to exceed its threshold 12 out of 29 months.
- CVS 5195 allowed to exceed its threshold 5 consecutive months.
- Caremed allowed to exceed its threshold 13 out of 17 months.[217]

This conduct is concerning when viewed in light of the information not only available to Cardinal Health but that which their people actually reviewed and had knowledge of. The slide below was created by Cardinal to provide "talking points" for the "abnormal" buying pattern of CVS 219 in Sanford, Florida.[218]

Even Christopher Forst, who is a pharmacist and was Director of quality/regulatory affairs, testified that he "would be uncomfortable selling that much to the store," referring to CVS 219.[219]

As mentioned above this same practice of exceeding thresholds was not limited to the above Florida pharmacies but also is evident in Cuyahoga and Summit Counties. I have reviewed a spreadsheet produced by Cardinal as "Records of orders placed by customers in the City of Cleveland, Cuyahoga County, and Summit County that were held by Cardinal Health's anti-

[217] *See* CAH_MDL_PRIORPROD_DEA12_00004353; Depo. of Christopher Forst at 312:22-320:9.

[218] *See* CAH_MDL_PRIORPROD_DEA12_00003244, 00003250; CAH_MDL2804_01103874, 01103875; and CAH_MDL_PRIORPROD_DEA12_00014224 at 00014248 para 46.

[219] *See* Deposition of Christopher Forst at 333:22-23.

diversion system."[220] The spreadsheet contains the dates pharmacies exceeded their thresholds and what action was ultimately taken with respect to the orders (*e.g.*, Cut, Released, or Reported). Based on the due diligence files produced, Cardinal frequently failed to conduct adequate due diligence with respect to orders placed by customers in Cuyahoga and Summit Counties that exceeded their respective thresholds for controlled substances. The table below identifies a small sample of the orders that were ultimately released and allowed to ship despite there being inadequately documented due diligence supporting the justification indicated for the release.[221]

Date of Threshold Event	Pharmacy	Controlled Substance	Result	Justification (CAH_MDL2804_00135242)	Due Diligence
6/30/2011	Pharmed Pharmacy (DEA# AP4581155), 24340 Sperry Drive, Westlake OH (Cuyahoga County)	Oxycodone	Released	"NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY"	None
9/28/2011	Pharmed Pharmacy (DEA# AP4581155), 24340 Sperry Drive, Westlake OH (Cuyahoga County)	Oxycodone	Released	"Order quantity consistent with order normal pattern" NOT UNREASONABLE QUANTITY, PATTERN, AND/OR FREQUENCY"	None
8/13/2017	Skilled Care Pharmacy (DEA# FS3760041), 9299 Market Place, Broadview, OH (Cuyahoga County)	Oxycodone	Released	"Order reviewed and released." "VARIATION CONSISTENT WITH BUSINESS MODEL - NO INDICATION OF DIVERSION"	None

[220] *See* CAH_MDL2804_00135242. *See also* CAH's Third Supplemental Responses to Plaintiffs' Combined Discovery Requests, App. D.

[221] *See*, *e.g.*, Due Diligence files produced by Cardinal Health for customers in the City of Cleveland, Cuyahoga County, and Summit County, CAH_MDL2804_00000015 –00001851, CAH_MDL2804_00094067–00094604.

4/27/2017	Pharmerica (DEA# BP5756323), 24165 Detroit Road, Westlake, OH (Cuyahoga County)	Hydrocodone	Released	"VARIATION CONSISTENT WITH BUSINESS MODEL - NO INDICATION OF DIVERSION"	None
8/30/2017	Pharmerica (DEA# BP5756323), 24165 Detroit Road, Westlake, OH (Cuyahoga County)	Oxycodone	Released	"Order reviewed and released." "VARIATION CONSISTENT WITH BUSINESS MODEL - NO INDICATION OF DIVERSION"	None

According to Christopher Forst, when an order is placed by a pharmacy or drug store that exceeds a predetermined threshold the particular order is automatically stopped.[222] This means that the order would not be filled until it was reviewed by a Cardinal Health employee and **a conscious decision was made** to release the order that exceeded the threshold.[223]

By setting a threshold for its respective customers Cardinal Health internally determined at what level a specific order would be triggered as potentially suspicious. Such a trigger under Cardinal Health's system then implements the KYC requirement and requires Cardinal Health to conduct due diligence to determine whether the triggering order can be shipped or not. Such due diligence must be appropriately documented in the respective customers' due diligence files to insure an adequate history of investigative activity.

ii. **Know Your Customer**

The KYC aspect of Cardinal Health's system was devised in a way to allow for the documentational support of the regulatory decision Cardinal Health is required to make for its customers. This system was intended to collect information from several differing functions including but not limited to: (a) new account approval process, (b) on-sight investigations, (c) additional internal research conducted on the customer, and (d) justifications for changes made and due diligence conducted related to any specific order or threshold change.

[222] *See* Deposition of Christopher Forst at 339: 9-24.

[223] *See id*.

Cardinal Health failures came not necessarily in the design of its KYC system but in the **operation** of the system. Due diligence files should be complete, accurate, and maintained on each customer to allow a registrant to have a sufficient understanding of each specific customer. These customer files also must be accessible to allow a registrant to use this information when it receives an order that it believes is potentially suspicious. Based on the information that I have reviewed Cardinal did not maintain sufficient KYC/due diligence files on each of its customers to establish sufficient knowledge of the customers.

Cardinal also separated its retail customers into two categories: (a) retail independents (RI) and (b) retail chains. During Policy Period #2 Cardinal treated retail chain customers different from retail independents as it relates to KYC/due diligence. Cardinal Health relied on chain customers to conduct their own due diligence and investigations related to potential suspicious orders and diversion concerns.[224] This practice continued even after Cardinal Health was told by the DEA in November 2009 that Cardinal Health "must exercise the same level of oversight with respect to retail chain pharmacies and retail independent pharmacies."[225] The CSA does not permit a registrant to delegate or shift the burden of maintaining effective controls to a third party, even if that third party is also a registrant. These practices were not sufficient for Cardinal Health to meet its obligations under the security requirement.

c. Policy Period #3 (2012 to Present):

Cardinal Health's third redesign of its SOM program (2012-present) occurred after the second enforcement action by the DEA. Cardinal Health asserted that this system was less subjective but in reality it was the contrary. The system that Cardinal implemented in 2013 continued to utilize both the threshold system and the KYC/due diligence component. However, Cardinal Health's revised system now based the thresholds solely on the individual customer's information without consideration for the population that it served or comparison to similar customers.[226] This was violative of Cardinal Health's own Standard Operating Procedures (SOP).[227]

Cardinal also developed working guidelines, or "General Work Instructions," that, according to Todd Cameron, are utilized more frequently by Cardinal and contain more "action oriented detail" than the Standard Operating Procedures.[228] [redacted]

[224] *See* Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00014053 at page 13; CAH_MDL2804_03262274, 03262438.

[225] *See* Correcting Declaration of Michael A. Moné, CAH_MDL_PRIORPROD_DEA12_00013747 at page 4; Depo. of Steven Morse, 113:8-13; Depo. of Christopher Forst, 33:9-34:5.

[226] *See* Depo. of Todd Cameron, 54-69.

[227] CAH_MDL_PRIORPROD_AG_0028694.

[228] *See* Depo. of Todd Cameron, 118:2-119:5.

family.[229] The amount a customer is allowed to receive above its threshold depends on the current

This is the first timeframe for which Cardinal Health has produced specific suspicious orders related to CT1 jurisdictions. Cardinal Health identified [redacted] suspicious orders for Summit and Cuyahoga Counties combined from 1/1/13 to present.[236] Cardinal Health's system was designed so that if a customer exceeded a threshold and had a suspicious order reported based on that breach Cardinal Health was not to ship any more of that base code/drug family to that customer until the threshold reset at the end of the monthly cycle or there was adequate due diligence done to clear the order and subsequent orders. [237] I was able to compare Cardinal's distribution data to the suspicious orders reported after 1/1/2013.[238] Additionally, I conducted a further review to

[229] CAH_MDL2804_00012244, 00012249-00012267.

[230] *Id*. at CAH_MDL2804_00012263-00012264.

[231] CAH_MDL2804_00012244.

[232] *Id*.

[233] CAH_MDL2804_00012953.

[234] CAH_MDL2804_02350970.

[235] CAH_MDL2804_00009412, 00009413.

[236] CAH_MDL2804_00000013.

[237] *See Deposition of Shirlene Justus*, July 13, 2018 at 86:14 to 88:6.

[238] CAH_MDL2804_00000012; CAH_MDL2804_00000014.

determine for which orders there was any[239] due diligence investigation (or review) conducted and documented prior to shipping any further products of this same drug family. Cardinal had repeatedly failed to conduct and document adequate due diligence to dispel the suspicious activity prior to shipping additional opioids of the same drug family. The chart contained in Schedule III shows that Cardinal Health continued to ship the same opioid drugs to customers who Cardinal Health had already determined were placing suspicious orders in CT1 [redacted] of the time ([redacted] orders), and of those orders, [redacted] ([redacted] orders) were shipped with no documented due diligence

3. Cardinal Health failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).

Cardinal Health timely reported zero suspicious orders in CT1 jurisdictions (Summit and Cuyahoga Counties, Ohio) from 1996 to at least 2008, based on the records provided. The ILR is an after-the-fact distribution report which is insufficient. Cardinal has not been able to produce suspicious orders that were reported to the DEA for CT1 during Policy Period #2 (2008-2012). However, it was Cardinal Health's practice not to report suspicious orders but to "report an order as suspicious when the customer appeared suspicious" and Cardinal Health was going to terminate service to that customer.[240] Waiting to the point of termination of a customer prior to reporting any suspicious orders related to the customer is not sufficient to meet the reporting requirement. This conclusion is supported by several documents produced by Cardinal Health. First, Cardinal's November 1, 2012 Audit Committee Meeting packet indicates that during fiscal years 2010 and 2011 Cardinal only reported [redacted] suspicious orders, respectively, nationwide. This is in stark contrast to the [redacted] increase of reported suspicious orders that allegedly occurred in 2012, according to the document.[241] Additionally, during this same period of time the Baltimore DEA office provided a presentation to Cardinal Health that, among other things, outlined that between 2008 and October 1, 2011, Cardinal did not report any suspicious orders of oxycodone products in Maryland.[242]

Finally, during Policy Period #3 Cardinal Health reported [redacted] suspicious order but continued to ship the same base codes to many of those customers.[243] Any additional orders from these customers without having been cleared would also constitute a suspicious order and should have been reported to the DEA as such. Also during the 2012-2015 timeframe, Cardinal's employee testified that Cardinal failed to report to the DEA approximately 14,000 separate suspicious orders from around the country. According to Mr. Cameron these were for "subbase

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[239] Whether the due diligence was sufficient or not is an additional consideration.

[240] *See Investigation Report of the Special Demand Committee*, CAH_MDL_PRIORPROD_HOUSE_0003331 at page 36; *also see Supplemental Declaration of Michael A. Mone*, CAH_MDL_PRIORPROD_DEA12_00014762 at page 8; *also see* CAH_MDL2804_3262274, 03262438.

[241] CAH_MDL2804_03262274, 03262438.

[242] CAH_MDL2804_02509732, 02509741.

[243] *See* "Know Your Customer" section above.

codes" which would generally be for more highly abused dosages.[244] Additionally, using any of the below methodologies, as described in the Expert Report of Craig McCann, it is apparent Cardinal Health failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.[245]

4. Cardinal Health failed to *stop shipment* of suspicious orders of controlled substances in violation of the requirement to *maintain effective controls against diversion* as set forth in 21 U.S.C.A. § 823(b)(1) [1970].

Again, the premise of the CSA is to ensure that when dealing with these controlled substances that are highly addictive in nature and dangerous that we do so in a way that best protects our communities. This is signified in the CSA's requirement to all registrants' to "maintain effective controls" against diversion. With this understanding, even if Cardinal Health had properly identified suspicious orders, its corporate policy from 1996 to 2008 was to ship anyway. This is a blatant failure to maintain effective controls to prevent diversion and a breach of their regulatory obligations as a registrant.

Being that I have not specifically seen any suspicious orders identified by Cardinal Health as being reported for customers in Cuyahoga and Summit Counties during Policy Period #2, I cannot say whether Cardinal Health shipped any orders into Cuyahoga and/or Summit Counties that Cardinal Health identified as suspicious. However, I can say that Cardinal Health during this timeframe did ship suspicious orders that should have been identified.[246]

During Policy Period #3 it appears as Cardinal Health did halt shipment of the orders which it identified as suspicious. However, it is my opinion based on what has been provided and set out in Schedule III that Cardinal Health continued to ship base code 9143 and 9193 to the same registrant after reporting a suspicious order. Such conduct would constitute a violation of Cardinal Health's duty to maintain effective controls against diversion.

B. McKesson Corporation

McKesson Corporation

Distribution Center: New Castle, Pennsylvania

DEA Registrant Number: [redacted]

Transactional Data Disclosed: Date Range: 10/01/04 – 6/30/2018[247]

[244] Depo. of Todd Cameron, pp. 268-271.
[245] *See* Section III ,"Identifying Suspicious Orders Distributed in CT1."
[246] *See* Section III.(A.)(2.) above.
[247] MCKMDL00579972; MCKMDL00478913; MCKMDL00409045; MCKMDL00606062.

Cuyahoga[248]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	[redacted]		
Hydrocodone			

Summit[249]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	[redacted]		
Hydrocodone			

1. Court Ordered SOMS Discovery Disclosures:

- *McKesson Corporation's Objections and Responses to Plaintiffs' Combined Discovery Requests* (07/31/2018);
- *McKesson Corporation's Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests* (11/30/2018);
- *McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests* (03/04/2019).
- *McKesson Corporation's Third Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests* (3/29/2019).

2. **SOMS Corporate Policy Disclosed:**

McKesson Drug Operations Manual – Section 55 (January 15, 1997)[250]

McKesson Corporation (hereinafter "McKesson") utilized this system from at least 1997 to May 2007. Section 55 outlines five different reports concerning a customer's purchases (Controlled Substances Sales Report, Controlled Substances Customer Purchase Report, Daily Controlled Substance Suspicious Order Warning Report, Monthly Controlled Substance Suspicious Purchases Report and the Monthly ARCOS Customer Recap Variance). (MCKMDL00651873 at 00651919-20). However, the output from these reports was rather basic. McKesson created daily and monthly reports that documented retrospective sales of controlled substances, including opioids, when those sales exceeded three times of that customer's 12 month purchase average for that base code. (MCKMDL00651873 at 00651919-20; 1/10/19 Gary Hilliard Depo. at 163:21-169:7). After it was generated, a hard copy of the report was mailed or faxed to the local DEA office. The reports that were generated were known as DU-45 reports. However,

[248] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 136.

[249] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 766.

[250] MCKMDL00651873.

it should be noted that McKesson has not been able to locate any DU-45 reports that were allegedly generated from the New Castle Distribution Center. (*McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests* at p. 10).

Lifestyle Drug Monitoring Program (May 2007)[251]

In May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP"). The LDMP was limited to four drug products (oxycodone, hydrocodone, alprazolam and phentermine).[252] For these four drugs, an 8,000 monthly dosage unit threshold was set for every customer nationwide.[253] Once the 8,000 dosage unit threshold was hit in a given month, a 3 level review process was to be triggered.[254] However, the LDMP had no mechanism to block orders once the 8,000 unit threshold was hit and an investigation was ongoing.[255] Therefore, despite the 8,000 unit threshold being hit by a particular customer, that customer was still permitted to place and receive orders for opioids, including oxycodone and hydrocodone.

Controlled Substances Monitoring Program (May 2008)[256]

In May 2008, McKesson launched the Controlled Substances Monitoring Program (hereinafter "CSMP"). The CSMP continued to apply monthly thresholds, however, under the CSMP monthly thresholds applied to all opioid products. Thresholds were initially set under the CSMP by reviewing the customer's 12 month purchase history for each base code, reviewing the highest month of purchases in that 12 month period, and adding a 10% buffer to that purchase amount.[257] Thresholds could then be adjusted thereafter through a process referred to as a threshold change request (hereinafter "TCR").[258]

[251] MCKMDL00355251.

[252] MCKMDL00355251.

[253] MCKMDL00355251.

[254] MCKMDL00355251 at MCKMDL00355252-00355255.

[255] 11/28/18 William Mahoney Depo. at 584:11-17.

[256] MCKMDL00518064.

[257] MCKMDL00267635 at MCKMDL00267641; MCKMDL00633917.

[258] MCKMDL00267635 at 00267649.

[259] MCKMDL00330099 at MCKMDL0033114.

[260] MCKMDL00437057.

[redacted]

3. **Enforcement Actions**

a. On August 4, 2006, DEA issued an Order to Show Cause with respect to McKesson's Lakeland distribution center for failing to maintain effective controls against diversion concerning opioid products. [262]

b. On November 1, 2007, DEA issued an Order to Show Cause against McKesson's Landover distribution center for failing to maintain effective controls against diversion concerning opioid products.[263]

c. On May 2, 2008, McKesson and DOJ entered into a settlement agreement wherein McKesson agreed to pay a $13.25 million dollar fine and agreed to make improvements to its controlled substances monitoring practices. The settlement involved allegations by DOJ that McKesson failed to maintain effective controls against diversion at six of its distribution centers.[264]

d. On January 5, 2017, McKesson entered into a settlement agreement wherein it agreed to pay a $150 million civil penalty for violation of the 2008 settlement agreement as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.[265] Moreover, as part of this settlement agreement McKesson accepted responsibility for failing to identify and report suspicious orders following the 2008 settlement agreement.[266]

4. **Suspicious Orders Reported in CT1 Jurisdictions**[267]

	Pre-Shipment Reporting	Post-Shipment Reporting
1996	0	

[261] MCKMDL00437057 at 00437059-60.

[262] MCKMDL00337001.

[263] MCKMDL00337001.

[264] MCKMDL00337001 at 00337013-14.

[265] MCKMDL00355349 at 00355352-53.

[266] MCKMDL00355349 at 00355352.

[267] MCKMDL00478912; MCKMDL00616425-26.

1997	0[268]	DU-45 Reports
1998	0	DU-45 Reports
1999	0	DU-45 Reports
2000	0	DU-45 Reports
2001	0	DU-45 Reports
2002	0	DU-45 Reports
2003	0	DU-45 Reports
2004	0	DU-45 Reports
2005	0	DU-45 Reports
2006	0	DU-45 Reports
2007	0	DU-45 Reports
2008	0	
2009	0	
2010	0	
2011	0	
2012	0	
2013	129 [269]	
2014	649	
2015	557	
2016	300	
2017	195	
2018	77 [270]	

5. **Due Diligence Conducted**

From at least 1997 to May 2007, there was no due diligence conducted by McKesson regarding potential suspicious orders of controlled substances. From May 2007 to May 2008, McKesson represented to DOJ that under the LDMP "customers will not be allowed to exceed the 8,000 monthly dosage limit until a due diligence review has been completed."[271] However, this is not how the program appears to have actually operated, and in fact, I have seen documentation indicating that customers were routinely permitted to exceed the 8,000 monthly dosage thresholds

[268] From 1997 through May 2007 it is possible that McKesson reported excessive orders by way of the DU-45 Report for pharmacies in CT1, however, as noted above none of those reports could be located by McKesson and McKesson's own employees have not viewed these reports as encompassing true suspicious orders. (*See* Gary Hilliard, Jan. 10, 2019 Deposition at 176:8-176:22; MCKMDL00510747). These reports solely listed shipments that had already occurred and did not report any orders pre-shipment.

[269] All of the suspicious order reports in 2013 occurred on or after August 1, 2013. The orders reported from 2013-2018 were orders blocked by McKesson and not shipped.

[270] The data I have reviewed runs through June 30, 2018 presently.

[271] MCKMDL00330924 at 00330926; also stamped MCK-HOI-002-0000001 at 0000003.

prior to a due diligence review being completed by McKesson.[272] Both the LDMP and CSMP had a tiered three level review process that was triggered once a customer met their monthly threshold. However, I have reviewed the multiple due diligence files produced for Summit and Cuyahoga Counties covering the time span of 2006 to Jan, 1, 2014 and found no evidence of a Level 2 or Level 3 review being conducted prior to January 1, 2014.[273] Under the CSMP, McKesson also included a Know Your Customer Process. Again, however, McKesson's due diligence files produced in this case show that for years this process was very rudimentary in nature and that there were very few substantive investigations being performed.[274] [redacted].[275] However, each of the red flags included beginning in this time frame should have been monitored by McKesson for many years prior. McKesson's failure to do so serves as additional evidence of its failure to exercise due care in preventing diversion of opioid products.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by McKesson has generally been substandard, at best. McKesson conducted no due diligence until 2007. Once a due diligence program was finally instituted to require a review before a customer's opioid dosage unit threshold could be increased, threshold increases were routinely authorized with little to no justification. Also, as McKesson regularly showed complete deference to threshold increase requests from chain pharmacies, the due diligence for those customers was consistently lacking. Therefore, while McKesson has had some sort of due diligence program in place since 2007, a review of those programs in practice make clear that for all practical purposes, McKesson's due diligence efforts have fallen short of what is required.

6. **Opinions Related to McKesson Corporation:**

McKesson Corporation failed to ***maintain effective controls*** against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970]. The bar graphs identified as Figures 15-26 in Schedule II to this report demonstrate a clear escalation of prescription opioids into Cuyahoga County and Summit County by dose, base weight, and MME.

There is no more effective control to prevent diversion than blocking a suspicious order before it is shipped. This notion is also consistent with DEA guidance that has been provided to industry for decades.[276] As discussed above, from at least 1997 to May 2008, McKesson had no controls in place to block suspicious orders before they were shipped. Thus, any controls that were

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[272] *See e.g.,* MCKMDL00540033.

[273]MCKMDL00496212-MCKMDL00496305; MCKMDL00555448-MCKMDL00555744; MCKMDL00568207-MCKMDL00568281.

[274] *Id.*

[275] MCKMDL00330099 at 00330126-130.

[276] (*See e.g.,* 1996 DEA Investigators Manual (CAH_MDL2804_02203346); DEA Memorandum, Legal Guidance on Reporting Suspicious Orders (March 1, 2007) (CAH_MDL_PRIORPROD_DEA12_00000609).

in place during this time period were completely ineffective in meeting the ultimate goal; the prevention of diversion.

With the launch of the CSMP in May 2008, for the first time McKesson established a process for blocking orders that were identified as suspicious. However, it is clear that from the time the CSMP was launched that McKesson's programs contained multiple loopholes to ensure as few orders as possible were blocked, thereby ensuring that the controls that were put in place remained completely ineffective. In fact, at the outset of the program McKesson notified all of its customers they should not expect any change in their ability to order controlled substances under the CSMP. In a document that was to be shared with McKesson's pharmacy customers when introducing them to the CSMP, McKesson stated "[t]his program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but it also ensures that you as a McKesson customer can continue with **business as usual**."[277] Given that this document was written just after McKesson entered into a $13.25 million dollar settlement with DOJ for failing to have effective controls against diversion as it pertained to opioid distribution, the message to McKesson's customers should have been that it would be anything but business as usual for them. However, unfortunately this mentality appears to have been pervasive within McKesson's regulatory department for years to come, contributing to the following significant shortcomings with its SOM programs.

First, while McKesson established thresholds under the CSMP, those thresholds were frequently set far too high to ever be triggered. In fact, in August 2014, DOJ pointed out this fatal flaw in McKesson's CSMP. DOJ noted that McKesson's review process under the CSMP was not even triggered until a customer purchased more than 10% of their average[278] ordering month in the prior 12 month period. Not to mention, these thresholds were set based on purchases from 2007-2008 which DOJ noted was a "year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies."[279] The extremely high thresholds set by McKesson for controlled substances did not go unnoticed within the company. On August 31, 2011, Director of Regulatory Affairs, David Gustin, noted "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases."'[280] Despite Mr. Gustin's concerns, no serious efforts were undertaken to systematically reduce

[277] MCKMDL00543610 at 00543613 (emphasis added).

[278] The reference to the thresholds being set based on the average orders from the prior 12 months also underestimates how McKesson actually set thresholds. According to McKesson's own documents, these thresholds were set based on the highest ordering month from the prior 12 months, not the average month. (*See e.g.,* MCKMDL00626898).

[279] MCKMDL00409224 at 00409234.

[280] MCKMDL00507799.

thresholds until 2015, a full four years later.[281] McKesson also continued to utilize a form of this system to set new thresholds until switching to the AGI based threshold algorithm in the 2017-2018 time period. In fact, the "business as usual" mentality noted above continued even after McKesson entered into a $150 million settlement with DOJ for its continuing failure to have effective controls against diversion following the 2008 settlement. Only two weeks after the settlement agreement was signed, McKesson's Senior Director of Regulatory Affairs, Nate Hartle, attempted to calm customer concerns that McKesson would be stricter on its supply of controlled substances by once again noting it would be "**business as usual from a threshold perspective**."[282]

Second, McKesson routinely increased thresholds without requiring adequate justification for the increases. In order to have a threshold increased under the CSMP, a customer was supposed to provide documentation supporting a legitimate change in business that warranted the threshold increase.[283] However, these requirements were routinely ignored. As an example, in April 2011, Director of Regulatory Affairs, David Gustin, expressed that McKesson needed to tighten up the process regarding threshold increases because threshold increases were "almost automatic" and being granted for insufficient reasons, like "business increase".[284] Regulatory Affairs Director Tom McDonald reiterated these concerns in July 2012. Mr. McDonald noted that the company was too liberally granting threshold increases without proper documentation and often based only a stated claim of business growth by the customer.[285] Mr. Gustin became so concerned about the lack of due diligence being conducted by McKesson that he even noted to other colleagues in regulatory affairs that "[w]e as DRAs need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time."[286] Another Regulatory Affairs Director, Michael Oriente, responded, "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up."[287] McKesson ultimately acknowledged the problem of deficient due diligence, especially as to threshold increase requests. A November 2013 training deck noted a desire to make threshold change increases "the exception, not the rule" going forward in order to address the lack of due diligence that had become the norm at McKesson related to threshold increase requests.[288] The lack of due diligence surrounding threshold increases was also apparent

[281] *See* MCKMDL00410744; MCKMDL00402184.

[282] MCKMDL00418094 (emphasis added).

[283] MCKMDL00267635 at MCKMDL00267649.

[284] MCKMDL00507221 at 00507223.

[285] MCKMDL00633455.

[286] MCKMDL00634329 at 00634331.

[287] MCKMDL00634329 at 00634330-31.

[288] MCKMDL00516748 at 00516754.

to DOJ. In August 2014, DOJ noted that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons.[289]

Third, McKesson has a long track record of absolute deference to retail national account customers when it comes to threshold increases. McKesson's Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances. (See Donald Walker Deposition; Jan 10, 2019; pp. 190-193.). These practices resulted in McKesson routinely granting threshold increases to retail national account customers without any apparent due diligence, including many pharmacies in Summit and Cuyahoga Counties.[290] McKesson's conduct in this regard was patently improper, as the duty to conduct due diligence is non delegable.

Fourth, McKesson took affirmative steps to reduce the number of controlled substance orders it would have to block by warning customers that they were approaching a threshold, so the customer could seek an increase before McKesson would be forced to block their orders. In fact, this threshold warning system was designed solely to ensure that thresholds could be increased before any sales were lost. In discussing the creation of these reports in October 2006 Sharon Mackarness of McKesson stated, "[w]e are in the business to sell product. If we could produce a report … that warned a customers approach to the threshold, say at 85% of their 10,000 dosages, work could begin on justifying an increase in threshold prior to any lost sales."[291] These threshold warning reports were utilized for years thereafter to great effect as a preemptive tool to increase thresholds before orders had to be blocked. Presumably understanding the impropriety of providing these warning reports to customers, in November 2013 McKesson announced to its employees a new policy pertaining to threshold warning reports. The presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time."[292] However, in the following months McKesson was already making exceptions to this newly established policy for customers in Summit and Cuyahoga Counties.[293] The shift to not providing these warning reports was proper and McKesson should have abided by this policy without exception.

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[289] MCKMDL00409224 at 00409235.

[290] *See e.g.,* MCKMDL00000497; MCKMDL00363951; MCKMDL00574488; MCKMDL00555448; MCKMDL00512974; MCKMDL00628614; MCKMDL00555473; MCKMDL00555484; MCKMDL00555501; MCKMDL00555506; MCKMDL00628660; MCKMDL00568233; MCKMDL00555480; MCKMDL00555536.

[291] MCKMDL00543971 at 00543972.

[292] MCKMDL00476786 at 00476791.

[293] *See e.g.,* MCKMDL00476692; MCKMDL00485800.

The above measures individually and collectively served to render McKesson's various programs ineffective as anti-diversion tools.

[redacted] However, McKesson had specifically been told to monitor for exactly that type of information by DEA as far back as 2005.[296] Similarly, in [redacted][297] However, this sort of geographic analysis had been encouraged by the DEA at least since 1996.[298]

McKesson has recently adopted a new threshold system developed by AGI. While it is too soon to determine if that program will be effective in preventing diversion, there is reason to be concerned that it is flawed as well. [redacted] That foundational construct is illogical given that it is the sales of opioids at these levels that has created the opioid epidemic and have resulted in McKesson paying significant fines for failing to maintain effective controls against diversion in 2008 and 2017.

2. McKesson Corporation failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the ***security requirement*** set forth in 21 C.F.R. § 1301.74(b).

a. Policy Period #1 (1997-May 2007)

Like Cardinal Health, McKesson claims the system it utilized from 1997 to May 2007 was premised upon guidance from the DEA. As previously noted, no guidance to justify McKesson's actions during this time period has ever been provided by the DEA. Nor does the record reveal any document which supports this contention. Moreover, McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders as required by the regulations. Multiple McKesson regulatory employees have acknowledged that the DU-45 reports were not meant to detect true suspicious orders. As discussed by McKesson's Regulatory Affairs Director, David Gustin, "the previous reports were not the exclusive and proper response to this regulation. We have an obligation to report 'suspicious orders.' With no clear definition of what constitutes a suspicious order we must rely on our own judgment as to what that is. If we report

[294] MCKMDL00330099 at 00330126-130.

[295] MCKMDL00330099 at 00330129.

[296] *See* MCKMDL00496859 at 00496862.

[297] MCKMDL00330099 at 00330129.

[298] *See* CAH_MDL2804_02203353 at 02203357.

anything we believe to be truly suspicious we will be meeting the spirit and letter of the regulation. Simply reporting larger than usual orders does not when there are so many plausible and routine reasons for orders to be 'larger than normal.'"[299] Further, another Director of Regulatory Affairs for McKesson, Gary Hilliard, has testified that McKesson's suspicious order monitoring system prior to 2007 was not designed to detect true suspicious orders.[300]

Additionally, because during this time period McKesson was reporting excessive orders it had already filled it made no effort to detect, investigate, or block any suspicious orders. Consequently, during this time period McKesson blatantly violated the ***security requirement*** set forth in 21 C.F.R. § 1301.74(b).

b. Policy Period #2 (May 2007-May 2008)

McKesson's LDMP did not fare better when it came to identifying suspicious orders. McKesson has been unable to produce any documentation of true suspicious orders being reported during this time period.

c. Policy Period #3 (May 2008-present)

McKesson's CSMP could have been used as a tool to report suspicious orders, but was not used in that fashion until five years after it was initially launched. For Summit and Cuyahoga Counties, McKesson failed to report a single suspicious order from May 2008 to July 31, 2013.[301] To put that into further context, during that time period McKesson filled approximately [redacted] opioid orders in these two counties.[302] This failure to report suspicious orders during this time frame is not an anomaly that is restricted to Summit and Cuyahoga Counties. As DOJ recognized, there was a "nationwide" and "systemic" failure of McKesson to report suspicious orders and otherwise maintain effective controls against diversion.[303] This conclusion is borne out by McKesson's failure to report any suspicious orders from its Livonia, Washington Courthouse, Lakeland, and Metheun distribution centers despite ample evidence of diversion occurring from customers of each of these distribution centers.[304] The egregiousness of McKesson's failure to report suspicious orders is further supported by the quantity of orders McKesson did report as suspicious once it finally decided to begin engaging in the practice. For example, in 2015 alone, McKesson has acknowledged it reported a total of 230,000 suspicious controlled substance orders nationally.[305] Similarly, the rise in suspicious order reports by McKesson in Summit and

[299] MCKMDL00510747.

[300] 1/10/19 Gary Hilliard Depo. at 176:8-176:22.

[301] MCKMDL00478912.

[302] MCKMDL00478913.

[303] MCKMDL00409453 at 00409454.

[304] *See generally* MCKMDL00409453.

[305] McKesson Board of Directors' Response to International Brotherhood of Teamsters at p. 24.

Cuyahoga Counties beginning in late 2013 cannot be supported by any conclusion other than that prior to that time McKesson completely and utterly failed to meet its regulatory responsibilities.

It is also apparent that McKesson's failure to report suspicious orders was not accidental or due to a misunderstanding of its regulatory duties. In fact, the term "suspicious" when it came to controlled substances was taboo within the company. At the time McKesson's CSMP was created in 2008 it included a section that advised employees to "[r]efrain from using the word 'suspicious' in communications"' because "[o[nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means that all controlled substances sales to that customer must cease and the DEA must be notified."[306]

Reporting Requirement:

McKesson failed to timely report suspicious orders in Summit and Cuyahoga Counties and nationally from at least 1997 to 2013. This is supported by the fact that McKesson's own regulatory employees have acknowledged that the excessive orders reported on the DU-45 reports were not synonymous with the type of suspicious orders outlined in the applicable regulations.[307] Moreover, even under the LDMP and CSMP McKesson continued its pattern of failing to report suspicious orders until finally beginning to do so in late 2013. Finally, the number of suspicious orders reported in Summit and Cuyahoga Counties beginning on August 1, 2013 and continuing to June 2018 is insignificant compared to the number of opioid orders McKesson has filled during that same time period in those counties. During that five year period, McKesson has reported a total of [redacted] suspicious orders in those two counties while also shipping [redacted] during that same time frame – less than one half of one percent of orders from Cuyahoga and Summit Counties.[308]

Further, using any of the methodologies as described in the Expert Report of Craig McCann, it is apparent McKesson failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.[309]

Shipping Requirement:

From at least 1997 to May 2008, McKesson failed to block any suspicious orders nationally. Due to its high thresholds for many customers, as noted above, McKesson has blocked an insignificant number of orders in Summit and Cuyahoga Counties after it began the practice in May 2008. For example, from May 2008 to June 30, 2018 McKesson has blocked a total of [redacted] opioid orders from Summit and Cuyahoga County customers.[310] However, during that same time

[306] MCKMDL00518064 at 005118078.

[307] Deposition of Gary Hilliard, 176:8-176:22; MCKMDL00510747.

[308] MCKMDL00675597; MCKMDL00675598; MCKMDL00478912; MCKMDL00616425; MCKMDL00616426.

[309] *See* Section III, "Identifying Suspicious Orders Distributed in CT1."
[310] MCKMDL00478912; MCKMDL00616425; MCKMDL00616426.

frame McKesson filled a total of [redacted] from those same two counties.[311] Based on this data, it is apparent that McKesson's systems have not been designed to properly block suspicious orders given the miniscule number of suspicious opioid orders that have actually been blocked during that time frame.

C. AmerisourceBergen Drug Corporation

Distribution Center: Lockbourne, OH

DEA Registrant Number: RA0314562

Transactional Data Disclosed: Date range: 2002-2018[312]

Cuyahoga[313]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

Summit[314]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

1. Court ordered SOMS Discovery Disclosure:

- AmerisourceBergen Drug Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests (3/4/2019)

2. SOMS Corporate Policy Disclosed:

(1) *Pre-2007 Overview.*

(a) The Threshold-Based System

Beginning as early as 1990, AmerisourceBergen Drug Corporation ("ABDC") utilized a threshold-based system to determine if an order is "excessive" (i.e. suspicious). In the deposition of Senior Vice President of Corporate Security and Regulatory Affairs, Christopher Zimmerman described the threshold history of ABDC's Suspicious Order Monitoring System. Mr. Zimmerman began his employment with ABCS in 1990 and from the time he began his employment until 1998,

[311] MCKMDL00675597; MCKMDL00675598.

[312] *See* Bates Nos. ABDCMDL00037402; ABDCMDL00037404, ABDCMDL00037406; ABDCMDL00279848-279853; ABDCMDL00306728-306729; ABDCMDL00308071; ABDCMDL00313653-313654; ABDCMDL00316111-316114.

[313] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 46.

[314] *Id*. at p. 676.

the threshold was described as being calculated through the following procedure: "You take all the pharmacies within that category and divide by the number of pharmacies to come up with an average volume for the month per drug category. And then there was a multiplier of three. Any order that was over the threshold amount would be produced an excessive order report."[315] Mr. Zimmerman made a clarification to the threshold calculation by indicating the "3" multiplier was used for Schedule II and Schedule III narcotic drugs (ARCOS reportable) and a "6" multiplier, or maybe higher, was used for Non-ARCOS drugs.[316] Mr. Zimmerman stated the controlled substances identified during that time period were shipped prior to being reported to the DEA in the excessive purchase report.[317] Such a policy constitutes a clear failure to maintain effective controls against diversion, as it entails shipping controlled substance orders identified as suspicious (or in this case, "excessive"), was not designed to identify orders of unusual frequency, or those that deviated from normal ordering patterns. Further, this system improperly utilized a factor of "3" and "6" to establish thresholds well above the calculated average for ABDC's customers.

During the time period of 1998 through 2007, ABDC implemented a new method of calculating thresholds. Mr. Zimmerman stated ABDC worked on a threshold project with the DEA for a two-year period from 1996 through 1998 to provide DEA with more accurate information. The threshold calculation was now calculated by using only a customer's four-month rolling average of that pharmacy's purchases and then apply a multiplier of three to "identify a trigger that would identify a suspicious order."[318] Again, such a policy constitutes a clear failure to maintain effective controls against diversion because ABDC continued to ship controlled substance orders identified as suspicious. In addition, the system failed to identify orders of unusual frequency, or deviating from a normal pattern, used a much shorter time period for calculating the threshold which would allow the average to increase faster, failed to compare like pharmacies purchasing activity, and utilized a factor of "3" to establish threshold well above the calculated average for ABDC's customers.)

ABDC's use of a threshold based system using a 3x multiplier derived from the DEA's Chemical Handler's Manual.[319] It is worth noting that these guidelines relate to "Listed Chemicals", rather than controlled substances, primarily focused on the sale of chemicals used to make illicit methamphetamine. "Suspicious orders" of Listed Chemicals are defined by 21 USC § 830(b)(1)(A) as orders of "extraordinary" size [based on a formula which multiples a monthly base weight average per base code by a multiplier (3x)]. Relying upon a threshold of "extraordinary" size fails to detect orders of "unusual size" and is not compliant with 21 CFR 1301.74(b). Nor is shipping suspicious orders after reporting. The Chemical Handler's Manual specifies that "when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicious. In addition to making the required reports, the transaction should not be completed until the customer is able

[315] *See* Zimmerman Deposition, 121:12-21.

[316] *Id*., 124:18-125:5.

[317] *Id*., 108:10-109:10.

[318] *See* Zimmerman Deposition, 122:18-23.

[319] Id., 131:7-133:22.

to eliminate the suspicions. The distributor may have to forego some transactions."[320] Despite this directive from the Chemical Handler's Manual, ABDC did not consider foregoing such transactions at the time.[321]

As discussed above, and pursuant to what a policy summary generated by ABDC after 2015 describes as its "Legacy Diversion Control Program,"[322] ABDC shipped all orders of controlled substances before ruling out the possibility of the orders being suspicious.[323] Only after shipping the orders did ABDC report any orders that it deemed to be suspicious to the DEA through an "excessive order report."[324] ABDC sent these reports on a monthly basis to the DEA.[325] ABDC took no other actions with regards to excessive orders prior to 2005, meaning that ABDC shipped all orders - including orders that may have been suspicious – without any further investigation or due diligence.[326]

The determination of whether an order is "excessive" *i.e.* suspicious, has always been determined by ABDC using a threshold-based system.[327] ABDC deemed an order to be "excessive" if it exceeded a "threshold."[328] In order to create thresholds, ABDC generally identified characteristics by which it could group its customers (this analysis changed over time), then made certain determinations based on ordering patterns (this analysis also changed over time) of its customers, and used that information to set a threshold of a drug that could be purchased without becoming suspicious.

While documentation of ABDC's suspicious order monitoring program prior to 2005 is scant, Mr. Zimmerman testified that it involved a two-step process: "It was an excessive order report that was produced monthly to send to DEA, and then we also had a manual process at the distribution centers where the order fillers would identify suspicious orders and report those."[329] ABDC's written policies and procedures indicate that at least as early as December 1, 2005, ABDC operated an "Excessive/Suspicious Order Investigation Program," to "review the ordering activity of its customers to identify possible excessive or suspicious orders of controlled substances and listed chemicals."[330] Although the system now allegedly provided for the identification and investigation of excessive orders, ABDC's system still identified these orders using a threshold.

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[320] *See* Chemical Handler's Manual, 2001 Edition, at p. 21.

[321] *See* Zimmerman Deposition, 143:9-145:2.

[322] *See* ABDCMDL00004578-4602.

[323] *See* ABDCMDL00000109 ("Historically Controlled Substance/ Listed Chemical order monitoring has been based on a ship and report process.")

[324] *See* Zimmerman Deposition, 110:16-22, 121:7-122:3.

[325] *See* Mays Deposition, Part I, 101:7-24; *see also* Zimmerman Deposition, 108:19-24.

[326] *See* Mays Deposition, Part I, 142:15-143:14.

[327] *See* ABDCMDL00004578, at 2-4, 7, 10-13.

[328] *See* Zimmerman Deposition, 121:7-21.

[329] *See* Zimmerman Deposition, 108:19-109:4.

[330] *See* ABDCMDL00359957-9961.

Therefore, the 2005 system was not new, it merely continued the threshold-based system that was in place prior to the newly written policy. And, although ABDC conflated concepts of "excessive" orders and "suspicious" orders by treating them identically, ABDC continued its policy of shipping such orders to its customers, despite internally identifying them as either excessive or suspicious.[331] While the 2005 policy and procedures document includes a new "investigation" component that was not previously present in ABDC's suspicious order monitoring system, this component was effectively ignored because, as noted above, ABDC confirmed that it shipped all orders prior to 2007 without investigating them or reporting them to the DEA.

(b) Discretionary and Subjective Components of the Threshold-Based System

In addition to the excessive order reports which included orders that exceeded the relevant threshold, employees in ABDC's distribution centers ("DCs") were provided with guidelines instructing them to report orders that were of an unusual size or frequency, or which deviated from the normal ordering pattern.[332] ABDC placed signs in the distribution center "cages" with the base quantity levels that could be ordered and it was left to a distribution center employee's discretion to determine whether an order was suspicious. ABDC's order monitoring system at the time also required that ABDC confirm whether customers had the appropriate licenses.[333]

At this time, ABDC employed the same monitoring policy across all of its customers, regardless of the type of customer, or whether they may have operated as "internet pharmacies."[334] Further, ABDC did not have any policies or procedures in place to compare its customers' purchase of controlled substances with the average purchases of similarly situated customers.[335] Rather, ABDC only "monitored the average of each customer against its own orders at that time."[336] Nor did ABDC have any system in place to monitor its purchasing of Schedule II or III controlled substances as it compared to other types of substances,[337] or any system to evaluate the frequency of orders of controlled substances placed by its customers[338].

Prior to 2007, ABDC did not have a clear hierarchy establishing responsibility for preventing diversion. They did not form their Diversion Control Group or Team until after 2007.[339] This group was later referred to as the Corporate Security & Regulatory Affairs Department ("CSRA"). Aside from the baseline numeric thresholds ABDC used to identify "excessive" orders, ABDC lacked clear objective standards for determining when orders from its customers were "suspicious." This was due, in part, to the fact that discretion was left to

[331] *Id*.

[332] *See* Zimmerman Deposition, 118:1-11.

[333] *See* Mays Deposition, 170-174.

[334] *See* Mays Deposition II, 57:16-58:15.

[335] *Id*., at 68:1-71:23.

[336] *Id*., at 68:19-69:2.

[337] *id*., at 72:1-5.

[338] *id*., at 72:22-73:3.

[339] *See* ABDCMDL00270533.

distribution center employees to gage what constituted a normal ordering pattern and when a customer's order deviated from that pattern.

(2) *Post-2007 Overview of the Order Monitoring Program (OMP).*

(a) The June 2007 DEA Enforcement Action and Settlement

The year 2007 marks a key shift in ABDC's suspicious order monitoring policies. That year, the DEA initiated an enforcement action against ABDC due to its filling and shipment of orders from internet pharmacies, which according to the DEA, ABDC knew to be suspicious.[340] The enforcement action shut down ABDC's Orlando distribution center. On June 22, 2007, ABDC and the DEA reached a settlement agreement regarding the Orlando distribution center, which acknowledged "AmerisourceBergen failed to maintain effective controls at the Orlando Facility against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain customers of AmerisourceBergen."[341] As a result, to obtain authorization from the DEA to re-open the Orlando facility, ABDC was forced to update its diversion control program, including adding (1) a more in-depth due diligence process; and (2) a requirement to stop shipping suspicious orders to customers.[342]

The settlement arose from failures in ABDC's suspicious order monitoring program, which were systemic because ABDC maintained national suspicious order monitoring policies and procedures.[343] According to an April 19, 2007 Order to Show Cause and Immediate Suspension of Registration issued by the DEA, ABDC distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers, distributed hydrocodone to pharmacies even though they ordered small amounts of other drug products relative to those purchases, distributed hydrocodone to pharmacies much more frequently than ABDC's other customers, and shipping to pharmacies that ABDC knew or should have known many prescriptions were issued by physicians who did not conduct a medical examination of its customers, and instead wrote prescriptions for controlled substances ordered by customers over the internet.[344] Thus, the settlement between ABDC and the DEA resulted in nationwide changes to ABDC's suspicious order monitoring program. Specifically, ABDC revamped its procedures and instituted its Order Monitoring Program (OMP).[345] The most significant change was ABDC no longer shipped orders to customers that ABDC identified as being suspicious.[346] The OMP primarily relied on static thresholds to determine whether an order was potentially suspicious and

[340] *See* ABDCMDL00269383-84.

[341] *See* ABDCMDL00279854.

[342] (*See* Zimmerman Deposition, 139:20-140:8; *see also* Settlement and Release Agreement, ABDCMDL00279854–00279865).

[343] *See* Mays Deposition II, 24:18-22.

[344] *See* ABDCMDL00269383-387.

[345] *See* generally ABDCMDL00000101.

[346] *See* ABDCMDL00270533.

should be investigated. If an order exceeded a threshold, it was flagged as an excessive or potentially suspicious order.[347] ABDC would not automatically designate an order that exceeded threshold as "suspicious."[348]

(b) The New Threshold System

To determine each customer's threshold under the 2007 system or "Legacy Diversion Control Program," (otherwise referred to as the OMP) ABDC grouped customers within a "Customer Type."[349] The "Customer Types" were based on how customers were registered with the DEA, e.g. hospital/clinic, retail pharmacy, distributor, etc.[350] ABDC would then classify each customer by its "Customer Size," which was based upon its total average monthly total revenue of prescription sales of both control and non-controlled drugs (as opposed to its purchasing pattern of a specific drug family) relative to its peers in the same "Customer Type."[351] Customer Sizes were small, medium, large, or extra-large.[352] Then, ABDC looked at the Customer Type, and Customer Size and created an average purchase among of each drug family within each Customer Size and applied the same 3x multiplier. Implementation of the arbitrary 3x multiplier, however, negates the effectiveness of an effective Suspicious Order Monitoring System. Each customer had its own threshold for each drug family that it purchased, as described below, that was based on the foregoing analysis.[353]

If a customer's order exceeded a threshold, ABDC placed it in "OMP review."[354] After an order exceeded threshold, all subsequent orders in the same family from that customer were rejected while the earlier order was in OMP review.[355] Each DC was responsible for "initial review of all orders in OMP review."[356] DC associates – sometimes referred to by ABDC as "responsible persons in charge" ("RPIC") – were initially responsible for this task. However, as ABDC's

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[347] *See* Zimmerman Deposition, 112:18-113:2; 119:1-6. ABDC has claimed during deposition testimony that these were "orders of interest" beginning as early as 2007. However, deposition testimony from ABDC employee Kevin Kreutzer confirms that there was no use of that terminology during this time period. *See* Kevin Kreutzer Deposition, 67-68, 91-93, 109 ("Q. Do you recall Mr. Hazewski using the words "orders of interest" in 2009 when he trained you? A. No, I do not"), 111-12, 115-117). This inconsistency between the recollection of ABDC's employees undercuts the credibility of ABDC's witnesses.

[348] *See e.g.*, ABDCMDL0000002411 ("Depending on certain circumstances, it may be deemed that order is suspicious."); s*ee also* Mays Deposition, 131:5-16.

[349] *See* ABDCMDL00000110.

[350] *Id*.

[351] *Id*.; *see also* ABDCMDL00002325.

[352] *See* ABDCMDL00002405-2418.

[353] *Id*.

[354] *See* ABDCMDL00000114.

[355] *Id*.

[356] *Id*. The RPIC generally was responsible for the DC level review, although there was not a clear definition by ABDC of who was supposed to be in charge of reviewing orders at the DC level

program evolved, this role eventually migrated up to the Distribution Center Compliance Managers. In 2007, the OMP allowed the DC associates to "review, release, or cancel potentially suspicious orders before they are shipped to customers."[357] Review at the DC level was based on "the knowledge of the customer and the order."[358] If the "DC can determine that the order is not suspicious, the DC will release the order," but if DC is unsure, the order will be flagged for investigation by members of the CSRA investigation team working under the Director of Diversion Control who were referred to as CSRA Investigators.[359] The CSRA personnel then would determine whether to report the order to DEA as suspicious. ABDC seemingly had no set, concrete rules or criteria for distribution center employees to determine what made an order of interest be elevated to CSRA or be released as not suspicious.[360] The DC associates maintained a number of different ways to resolve questions regarding orders. However, if a DC cancelled an order (meaning that it would not be filled by the DC – with or without being reported to the DEA), or released an order (meaning it was approved for processing and shipped to the customer), the DC was required to log into the system with an explanation of why the action is being taken.[361]

A customer who was repeatedly going over threshold, or whose business was growing could request a "threshold review" to have its threshold adjusted. If approved, a threshold adjustment was referred to internally at ABDC as a "Threshold Override." The procedure for submitting a threshold review began when ABDC's sales teams, who were responsible for acquiring new customers and managing existing customers, submitted threshold review forms to the CSRA Department. The ABDC sales associate (from the sales team managing customer accounts) would request the threshold reviews for the customers.[362]

(3) *FTI Consulting, Inc. Audit of ABDC Compliance Activities.*

In August 2015, ABDC voluntarily engaged an outside consultant – FTI Consulting, Inc. ("FTI") - to review its order monitoring system. FTI issued a report documenting the findings of an audit of ABDC's compliance activities.[363] The FTI report disclosed numerous problems, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs.[364] In addition to the report, for various areas within the company, including Diversion Control, a forty-five page

[357] *See* ABDCMDL00002325.

[358] *See* Mays Deposition, 220:11-14; *see also* Zimmerman Deposition, 457:1-459:19.

[359] *Id*.; *see also*, ABDCMDL00046622.

[360] *See* ABDCMDL2405-2418 (describing the DC review process as "arbitrary"); *see also* ABDCMDL00250024-250063.

[361] *See* ABDCMDL00002325.

[362] *See* Elkins Deposition, 245:2-246:6.

[363] *See* ABDCMDL00274105-18.

[364] *Id*.

chart discussed "findings & observations," "Gaps & Risks," and "Recommendations."[365] Notably, a "Gap & Risk" concerning ABDC's Diversion Control program included "[r]egulatory obligations related to diversion control."[366] David May, ABDC's senior director of Diversion Control, testified that in response to the report, ABDC took no actions and made no changes to its diversion policies or procedures.[367]

Despite this willful failure to address specific deficiencies in its OMP, evidence collected thus far shows that ABDC understands the importance of diversion control. For instance, David May testified that the company has "anti-diversion programs in place to prevent the misuse and abuse of controlled substances."[368] Similarly, Chris Zimmerman, ABDC's chief compliance officer, acknowledged, "if we don't adhere to our effective controls to prevent diversion, yes, diversion could occur."[369] As discussed above, however, the evidence shows that ABDC consistently ignored critical red flags and warning signs from its customers in what amounts to a structural break-down of its diversion prevention obligations under the CSA, which had real consequences in the communities where ABDC does business.

For example, a DEA suspension order concerning one of ABDC's Ohio customers, East Main Street Pharmacy, documented deaths that occurred as a result of a failure to prevent diversion.[370] Ms. Julie Fuller, an ABDC sales representative who was responsible for East Main Street Pharmacy, testified in the suspension proceedings. Notwithstanding the obvious signs of illegal activity occurring at the East Main Street Pharmacy, including the fact that more than half of the pharmacy's prescriptions were written by an out-of-area doctor who was writing high volumes of controlled substances, Ms. Fuller "acknowledged that the purpose of her visits was not 'to observe [the pharmacist]' in the practice of pharmacy but to get his business."[371] Subsequent to the suspension proceedings, Ms. Fuller signed a Declaration, where she stated that as an account manager, ABDC only provided her general sales training, and did not provide any training or information on (a) how to identify questionable pharmacy behavior like suspicious dispensing, sales, or prescription filling practices, (b) how to report concerns regarding those behaviors, or (c) how to ensure that account managers only signed up and maintained accounts with legitimate pharmacies.[372]

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[365] *See* ABDCMDL00250024-63.

[366] *Id*.

[367] *See* May Deposition, 149:2-5.

[368] *See* May Deposition, 97:22-98:1.

[369] *See* Zimmerman Deposition, 104:14-17.

[370] *See* https://www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr1027_3 htm.

[371] *Id*.

[372] *See* Declaration of Julie Fuller, ¶ 9 (PLTF_2804_000004483).

3. Suspicious Orders Reported In CT1 Jurisdictions:[373]

	Pre-Shipment Reporting	Post-Shipment Reporting
2007	0	0
2008	0	0
2009	1	0
2010	18	0
2011	25	0
2012	45	0
2013	167	0
2014	20	0
2015	3	0
2016	0	0
2017	0	0
2018	0	0

4. Due Diligence Conducted:

On August 10, 2005, the DEA met with Steve Mays, ABDC's then-Director of Regulatory Affairs, to inform him about the common characteristics of pharmacies that divert large amounts of controlled substances by filling invalid prescriptions obtained by customers using the internet.[374] Prior to that meeting, ABDC's due diligence policy consisted solely of "a good faith effort to make sure that that customer's properly licensed with the state and registered with the DEA."[375]

As a result of the 2005 DEA meeting, ABDC began using a questionnaire to obtain information about its customers as part of a new due diligence effort, which consisted of 10-12 questions, but they were "all related to internet pharmac[ies]."[376]

After the 2007 DEA enforcement action, ABDC implemented a "Know Your Customer" due diligence policy. ABDC's due diligence program was effectuated through the Form 590 retail

[373] *See* ABDCMDL00379672; ABDCMDL00379673; ABDCMDL00383973; ABDCMDL00379674; ABDCMDL00383974.

[374] *See* ABDCMDL00269383-387.

[375] *See* Mays Deposition II, 73:24-74:21.

[376] *See* Mays Deposition 134:16-135:16; Mays Deposition II, 37:1-15.

pharmacy questionnaire. The Form 590 was supposed to be filled out by ABDC's customer sales representatives in conjunction with ABDC's pharmacy customers. ABDC's witnesses testified that the Form 590 is and was an important component of its diversion control program.[377]

The Form 590 process, however, suffered from numerous deficiencies. First, for many years, the Form 590 was only for new customers.[378] None of the requisite due diligence information was collected for existing customers.[379] Additionally, ABDC exempted "retail chain pharmacies" (broadly defined to include pharmacies with 10 or more locations, or any number of locations in more than one state) from the Form 590 requirement.[380] Rather than require all pharmacies within a chain to complete a Form 590, ABDC allowed the chain to complete one Form 590. This exempted large swaths of ABDC's customers from the requirement of completing Form 590.

Moreover, documents show that even when Form 590s were required, vast numbers of the forms were either illegibly filled out or contained substantial omissions.[381] Indeed, David May acknowledged that the "continued deficiency [in the Form 590s] puts us at risk with regulators."[382] In 2016, ABDC implemented a "CSRA 590 Validation Project" to "validate that all ABDC customers authorized to purchase controlled substances and identify any with deficiencies"[383], but one year into the project, ABDC had only received "about 10% percent of the required customer due diligence documents."[384] To date, as of May 29, 2018, ABDC estimates that only about 60% of the due diligence deficiencies have been remedied.[385] The lack of both current and historical documentation of due diligence efforts are indicative of a failure to maintain effective controls to prevent diversion.

In 2013, ABDC's due diligence efforts were the subject of a DEA audit and subsequent investigation. According to Joseph Tomkiewicz, an investigator and diversion program manager at ABDC, DEA agents met him at his personal residence sometime in the fall of 2013. This resulted in conversations with the U.S. Attorney about ABDC's due diligence efforts, specifically whether it had truncated the Form 590 for a specific group of pharmacies, which investigators believed may have short-circuited ABDC's customer due diligence process.[386] This point is also reflected in an ABDC "DEA Audit History" spreadsheet, with notes that indicate: "DEA was not

[377] *See, e.g.*, May Deposition, 263:8-19.

[378] *See* Zimmerman Deposition, 213:10-17.

[379] *Id*.

[380] *See, e.g.*, ABDCMDL00000107; *see also*, Zimmerman Deposition, 213:16-214:9.

[381] S*ee* May Deposition, 269:12-20.

[382] *See* ABDCMDL00159415.

[383] *id*.; May Deposition, 272:8-13.

[384] *Id*., at 273:21-24.

[385] *Id*., at 283:24-284:23.

[386] *See* Tomkiewicz Deposition, 35:10-23; 57:2-16:14; *see also* WAGMDL00237263.

comfortable with the [OMP] program and analyzed the program specifically how customers are screened."[387]

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by ABDC has fallen short. First, ABDC conducted no due diligence until 2005. Once a due diligence program was finally instituted, it consisted of merely a short questionnaire and checking to confirm that the customer's licenses were current. Moreover, ABDC's initial due diligence program only addressed internet pharmacies. Later, even when the due diligence was conducted more broadly, it focused on new customers and, like some other wholesale distributors, ABDC regularly showed complete deference to chain pharmacies. Therefore, the due diligence for those customers was consistently lacking. Finally, more recently, it was uncovered that ABDC did not have any of the requisite due diligence files for significant numbers of its customers, calling into question whether any due diligence was actually conducted. In my opinion, while ABDC has had some sort of due diligence program in place since 2005, a review of those programs in practice make clear that for all practical purposes, ABDC's due diligence efforts have fallen short of what is required.

5. Opinions Related to AmerisourceBergen:

1. AmerisourceBergen failed to maintain effective controls against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].

The bar graphs identified as Figures 27-38 in Schedule II to this report demonstrate a clear escalation of prescription opioids into Cuyahoga County and Summit County by dose, base weight, and MME.

Documents produced by ABDC show that rather than focusing on putting effective controls to prevent diversion in place and designing and operating a system to detect suspicious orders and stopping those orders ABDC circumvented the requirements and coached customers on how to avoid being detected by the system and being the subject of an enforcement action by the DEA. For example, a July 2013 ABDC document entitled "Sales Talking Points" stated as follows:

> I am rather concerned about your pharmacy for a different reason. Based on your overall volume with us, your percentage of C2 orders is high and may be deemed suspicious by either our OMP system or regulatory authorities. ***This puts your account with ABDC at significant risk of closure or exposure to regulatory and enforcement agencies actions.***
>
> Every day, we read about another independent pharmacy under investigation. ***I want to make sure that doesn't happen to you.*** The

[387] ABDCMDL00253869.

> way I see it, is that you have a couple of options. First, you can make ABDC your primary wholesaler and shift all purchases to us. The second option is we arrange a short-term transition process and you stop buying C2s from ABDC and shift them to whomever your buying other products. The third option would be to do nothing -- but this is not a feasible long-term decision -- and its not a good option for anyone.[388]

2. AmerisourceBergen failed to stop shipments of suspicious orders of controlled substances in violation of the requirement to maintain effective controls against diversion as set forth in 21 U.S.C.A. § 823(b)(1) [1970].

ABDC's official national policy from 1990, up until the DEA Settlement in 2007, was to ship all orders of controlled substances, regardless of size, frequency, deviations from prior orders, deviations from averages, deviations from defined thresholds, or whether that order was determined to be suspicious. This is a blatant violation of the No-Shipping Requirement.

Further, while ABDC purported to change its system in 2007 pursuant to its settlement agreement with the DEA, it still did not fully comply with the No-Shipping Requirement after that date. For instance, the one suspicious order from Summit County ABDC reported to the DEA in 2010 was shipped anyway, rather than held or cancelled.[389] Likewise, one of the 12 suspicious orders from Summit County ABDC reported to the DEA in 2012 was shipped as well.[390]

3. AmerisourceBergen failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).

Pre-2007, ABDC's suspicious order monitoring system failed the security requirement set forth in 21 C.F.R. § 1301.74(b). Specifically, ABDC's pre-2007 policies constituted a failure to design and operate a system to identify suspicious orders because they only identified "excessive" orders that exceeded a 3x threshold, which only took into consideration prior orders of that specific pharmacy. ABDC's OMP system did not take into consideration other relevant factors such as order frequency patterns, order averages of similar pharmacies, or comparisons of sales of Schedule II or III controlled substances with the sales of other controlled substances. ABDC also had no meaningful due diligence process in place to investigate whether such "excessive" orders otherwise qualified as suspicious, other than an effort to make sure a customer was licensed with the state and registered with the DEA. As evidenced by the 2007 DEA Enforcement Action which suspended the registration of ABDC's Orlando distribution facility, ABDC also specifically failed

[388] ABDCMDL00278212 (emphasis added).

[389] *See* ABDCMDL00379674; ABDCMDL00308070.

[390] *See* ABDCMDL00383974.

to identify suspicious orders from internet pharmacies that the DEA concluded should have been identified.

Post-2007, ABDC failed to design and operate an adequate system to identify suspicious orders because it continued to employ a "threshold-based system," which was based on an arbitrary "3x multiplier" among drug families, which again ignored other relevant information. ABDC also left critical discretion to identify suspicious orders with its distribution center employees, without putting in place any set, concrete rules or criteria on how suspicious orders should be identified. The 2015 FTI Audit Report also revealed numerous problems with ABDC's system, including a lack of resources, a lack of formal training, overburdened workloads, crushing administrative demands, inconsistent policies, and communications break-downs, which contributed to "gaps and risks" in ABDC's ability to identify orders as suspicious and prevent diversion. ABDC's efforts of due diligence in identifying suspicious orders at this time also fell well short of effective. Specifically, the "Know Your Customer" due diligence policy was based on a form filled out by ABDC's own sales representatives in conjunction with ABDC's pharmacy customers, creating a conflict of interest in identifying accurate information. The fact that ABDC's chain retail pharmacy customers were exempt from this requirement abdicated ABDC's duty to identify suspicious orders to the customers themselves. Further, the Form 590 due diligence program itself was inconsistently implemented, leaving a lack of current and historical documentation of due diligence efforts that renders a robust, effective due diligence system impossible.

4. AmerisourceBergen failed to *report* suspicious orders of controlled substances in violation of the *reporting requirement* set forth in 21 C.F.R. § 1301.74(b).

Between 1998 and 2008, AmerisourceBergen timely reported zero suspicious orders from the CT1 jurisdictions. This is a blatant violation of the Reporting Requirement. Further, using any of the methodologies described in the Expert Report of Craig McCann, it is apparent AmerisourceBergen failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.[391]

[391] *See* Section III, "Identifying Suspicious Orders Distributed in CT1."

D. CVS Health

Distribution Center: CVS Indiana, L.L.C.
7590 Empire Drive, Doors 116-123
Indianapolis, Indiana 6219

DEA Registrant Number: RH0197170

Distribution Center: CVS Rx Services, Inc.
150 White Wagon Road
Chemung, New York 14825

DEA Registrant Number: RC0415871

Transactional Data Disclosed:

Date range: 2002 to October, 2014 (when CVS quit distributing HCPs).[392]

Volume:

Cuyahoga[393]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

Summit[394]	Total Dosage	MME	Base Weight
Oxycodone	[redacted]		
Hydrocodone			

1. Court ordered SOMS Discovery Disclosure:

- *CVS HEALTH CORPORATION'S OBJECTIONS AND RESPONSES TO PLANTIFFS' FIRST SET OF INTERROGATORIES (6/18/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERRROGATORIES NO. 1-6, 8-10, 13, 15-18, 20-21 AND 30 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (9/10/18)*
- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NO. 11, 13 AND 30 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (11/30/18)*

[392] CVS-MDLT1-000003782–7364.

[393] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 181.

[394] *Id*, at p. 811.

- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORIES NO. 7, 12, 14, 15, 17, 19, AND 22-29 OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (1/25/19)*

- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO INTERROGATORY NO. 15. OF PLAINTIFFS' FIRST SET OF INTERROGATORIES (3/4/19)*

- *CVS HEALTH CORPORATION'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS (6/18/18)*

- *CVS INDIANA, L.L.C.'S AND CVS RX SERVICES, INC.'S AMENDED OBJECTIONS AND RESPONSES TO REQUESTS NO. 1-6 AND 9 –33 OF PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS (9/27/18)*

- *CVS RX SERVICES, INC.'S AND CVS INDIANA, L.L.C.'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' (FIRST) COMBINED DISCOVERY REQUESTS TO NATIONAL RETAIL PHARMACY DEFENDANTS (11/30/18).*

- *CVS INDIANA L.L.C. AND CVS RX SERVICES, INC. DISCOVERY RULING NO. 15 SUPPLEMENT (2/22/19)*

- *CVS INDIANA L.L.C.'S AND CVS RX SERVICES, INC.'S WRITTEN RESPONSE TO TOPIC 1 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/8/18)*

- *CVS'S WRITTEN RESPONSES TO TOPICS 8, 9, 12, 13 AND 14 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/15/18)*

- *CVS INDIANA L.L.C.'S AND CVS RX SERVICES, INC.'S PARTIAL WRITTEN RESPONSE TO TOPIC 2 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (11/19/18)*

- *CVS'S WRITTEN RESPONSES TO TOPICS 2, 4, 10, 16 AND 17 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6) (1/14/19)*

2. SOMS Corporate Policy Disclosed

It is my understanding that in response to the Combined Discovery Request No. 2, CVS listed Bates stamp ranges of documents but failed to identify with specificity the SOM policy

and/or procedure and/or the date said policy and/or procedure was in effect. Additionally, I understand that portions of the SOMS Corporate Policy were disclosed in the written responses to other discovery, the Rule30(b)(6) testimony offered by Mark Vernazza and the testimony of other deponents.

CVS's first written controlled drug operating procedures were circulated on December 1, 2007. The 2007 document was titled "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manual."[395] The "standard operating procedures were prepared in response to a need for a single source of current information for CVS regarding DEA policies and requirements of the Comprehensive Drug Abuse Prevention Act."[396] Although the "Suspicious Order Monitoring (SOM)" section of the standard operating procedures contained some language, albeit admittedly incomplete as outlined in the document, Mark Vernazza, the CVS 30(b)(6) witness and CVS in-house attorney, testified that the suspicious order monitoring section of the standard operating procedures was essentially a draft or placeholder and was not the policy that was necessarily in place at the time.[397]

In fact, despite admitting in 2007 that a need existed for a "single source of current information for CVS regarding DEA policies," CVS did not insert a written SOM policy into the standard operating procedures until August 25, 2010.[398] In other words, CVS had no written SOM policies until August 25, 2010. . Although denied by Vernazza, it appears that the August 25, 2010 SOM section of the Standard Operating Procedures was rushed into place to comply with a DEA request and the section shows a disregard for the necessity and importance of the SOM process, a fact demonstrated in the inconsistencies of the document itself.[399] For example, the title headings found within the Table of Contents for the SOM section do not actually match the title headings used in the document.[400] The page numbers in the Table of Contents for the SOM section are incorrect. Another example is the,wording of the SOM section itself is inaccurate, indicating that within the next month the critical Item Review Report ("IRR") examination process would be transitioned to each pharmacy DC and outlining procedures to be followed once that happens.[401] Yet the IRR review process was never transitioned to each individual DC. The Controlled Drug – DEA Standard Operating Procedures Manual for the pre-2014 SOM system was amended multiple times between 2010 and 2013, with the last revision dated April 18, 2013.[402] None of these amendments made significant changes to the SOM section, other than the March, 11, 2011

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[395] CVS-MDLT1-000025206-000025259.

[396] CVS-MDLT1-000025207.

[397] Vernazza Depo., 214:11–215:10; 219:4–221:13; 305:16–306:5; CVS-MDLT1-000025206–000025259.

[398] Vernazza Depo., 305:16–306:5; CVS-MDLT1-000008964–9032.

[399] Vernazza Depo., 300:6- 312:20; CVS-MDLT1-000089188; CVS-MDLT1-000057751.

[400] *See* titles found on CVS-MDLT1–00008966 compared with titles used at CVS-MDLT1-00009003.

[401] *See* CVS-MDLT1-00009004: "During the month of September, 2010, the report will be transitioned to each pharmacy DC and the following procedures will occur."

[402] CVS-MDLT1-00008572-000008635.

revision indicated the IRR review was centralized in Knoxville, TN,[403] and later revisions identified individuals who were supposedly fulfilling certain DEA obligations within CVS.[404] An example of this is the testimony of Amy Propatier who admitted that she was listed as the CVS DEA Compliance Coordinator in the Controlled Drug – DEA Standard Operating Procedures Manuals but that title was only for reference in the Standard Operating procedures and was not her real job position. She also testified that as the CVS DEA Compliance Coordinator the only thing she ever did related to suspicious order monitoring was updating the standard operating procedures manual.[405]

Despite the fact that the Controlled Drug – DEA Standard Operating Procedures Manual purported to be the "single source of current information for CVS regarding DEA policies,"[406] CVS did author other shorter policies that appear not to have been implemented or, at least, not consolidated with the "single source" SOP. Many of these shorter policies appear to be the same or very similar to the information contained within the CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manuals.[407]

On February 29, 2012, the first Work Instructions for Loss Prevention Analyst, outlining how to perform IRR/SOM analysis was instituted.[408] This appears to be the first written instructions informing analysts how to perform an IRR review. The IRR is the primary SOM process, and yet CVS neglected to provide written instructions outlining how to perform that critical review from its initial use in mid-2009 until February 29, 2012.

The DEA was on-site at CVS in August, 2013 conducting an investigation.[409] The content of the CVS letter to Mr. Gillen, who was the Diversion Group Supervisor for that DEA office, indicates the purpose was a regulatory investigation. This is an investigation of compliance with DEA security and record-keeping regulations and an accountability audit of selected controlled substances. Normally the DEA conducts a "closing" upon completing the investigation but according to the CVS letter, it still had not occurred as of November 21, 2013.

The CVS letter indicates that CVS and Mr. Gillen had a discussion on November 14, 2013 and Gillen had some concerns about the SOMS process. According to the CVS letter, Gillen was going to report to his Program Manager in Chicago that CVS had no reporting structure in place.[410] Trying to placate Mr. Gillen's concerns, Mark Nicastro sent a packet of information to the DEA.

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[403] CVS-MDLT1-00008413-00008482.

[404] See for example names inserted into the 5/6/11 Controlled Drug – DEA Standard Operating Procedures Manual found at CVS-MDLT1-00003177-3242.

[405] Propatier Depo., 79:15 – 81:2.

[406] CVS-MDLT1-000025206-000025259, 000025207.

[407] See PSE and Control Drug Policy & Procedures Template Logistics IRR Analyst – Suspicious Transactions (21 USC 830(b)(1) Effective Date: June 28, 2011. CVS-MDLT1-000083552-83556.

[408] CVS-MDLT1-0000020426–20428.

[409]CVS-MDLT1-000010202.

[410] CVS-MDLT1-000010202.

[411] [412] As part of the packet, CVS provided the DEA with what it claimed was its Standard Operating Procedure for Suspicious Order Monitoring but it provided an outdated version of the policy when a more recent edition was available. Specifically, on January 7, 2013 the "SOM Process—Stop Order/Order Resumption SOP" was drafted.[413] Revision number three of this document was dated three days later on January 10, 2013.[414] All of the evidence indicates that this was also a draft,[415] but CVS sent this document to the DEA on November 21, 2013 and portrayed it as the Standard Operating Procedure for Suspicious Order Monitoring.[416] A final revision of the Stop Order/Order Resumption SOP was created on March 28, 2013.[417] Months before CVS sent the packet to Gillen. In other words, CVS represented to the DEA that the January 10th version was the standard operating procedures for suspicious order monitoring, even though it had already been revised and supplanted. Moreover, all of the versions of the "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manuals" indicate that they are the "single source" for DEA policies, and they differ from the stand alone Standard Operating Procedure for Suspicoius Order Monitoring document provided to the DEA.

Significant differences exist between the January 10th version provided to the DEA on November 21, 2013 and the March 28, 2013 version that according to the documents was actually the version in place as of November 21, 2013. The January 10, 2013 CVS document (hereinafter referred to as Document A) provided to the DEA on November 21, 2013, was titled, "CVS / Corporate Logistics, External Documents, SOM Process – Stop Orders / Order Resumption SOP" with a Current Revision Date of 01/10/2013 and assigned Revision Number 03.[418] The more recent CVS policy that, according to the documents was in place on November 21, 2013 and should have been sent to the DEA (hereinafter referred to as Document B) was titled, "CVS / Corporate Logistics, External Documents, SOM Process – Stop Orders / Order Resumption SOP" with a Current Revision Date of 03/28/2013 and assigned Revision Number 04.[419] It should be noted both policies contain the following statement underlined in bold font, "**THIS IS A CONTROLLED DOCUMENT – USE LATEST REVISION**."

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[411] CVS-MDLT1-000010201 – 10212.

[412] The document as provided to Mr. Gillen representing suspicious orders reported by CVS to the DEA has insufficient information that renders it useless. The database does not identify the date of order, DEA registration #, type and strength of drug and/or NDC #.(CVS-MDLT1-000010209)

[413] CVS MDLT1-000028391-000028393. This document was a rough draft. See CVSMDLT1-000028390.

[414] CVS-MDLT1-000010205-000010208.

[415] See email string attaching document and corrections made which created another revision number 3, but that revision number 3 is dated 1/21/13. (See CVS MDLT1-000025365-000025369).

[416] CVS-MDLT1-0000010201–000010212.

[417] CVS-MDLT1-0000030545–000030548.

[418] CVS-MDLT1-000010205 -000010208

[419] CVS-MDLT1-000030546-000030548

The most significant difference was in regards to the due diligence process. In Document A in the Identify and Hold Section of the policy the second paragraph contains the following language:

> *Once an order of interest is identified, the SOM Analyst will complete all necessary due diligence and the SOM Manager will be notified to review the order. Due diligence will include, but is not limited to: contacting the Pharmacist, reviewing dispensing data, reviewing prior ordering data, comparing the quantity of controlled substances to non-controlled substances, determining if prescriptions for cocktails are being presented to the store, determining if one or several doctors make up a disproportionate share of the dispensing at the pharmacy, and contacting pharmacy operations to verify the information received from the store and to obtain any relevant information they may have about prescriber, nearby clinics, changes in the competitive landscape, or changes in the circumstances such as a new emergency room or clinic opening nearby that might impart the ordering history. If the SOM Manager agrees that order is an order of interest, the Distribution Center will be contacted, both by email and telephone, by the SOM Manager to place a Hold on the drug family in question on the order of interest and the SOM Manager will communicate to the Distribution Center each day to hold future orders for the store in question until the order of interest is verified. Once the order of interest is placed on hold, the process enters phase two, Review and Research.*

In Document B the second paragraph of the policy contains the following language:

> *Once an order of interest is identified, the SOM Analyst will complete all the necessary due diligence, according to the SOM Due Diligence SOP, and the SOM Manager will be notified to review the order. Due diligence will include, but is not limited to: contacting the Pharmacist, reviewing ordering date, etc. If the SOM Manager agrees that the order is an order of interest, the Distribution Center will be contacted, both by email and telephone, by the SOM Analyst to place a Hold on the drug family in question on the order of interest. Also, the SOM Analyst will communicate to the Distribution Center each day to hold future orders until the order of interest is verified. Once the order of interest is placed on hold, the process enters phase two, Review and Research.*

The language in Document A provides a very comprehensive description of the type of due diligence investigation required to review an order identified by the CVS system as potential suspicious orders when compared with Document B. The differences in language have a strong potential to render a different decision in regards to the effectiveness of the due diligence investigation. Document B contains the additional statement, "according to the SOM Due Diligence SOP." Document B does not specifically identify where to find the SOM Due

Diligence SOP. There is no mention of due diligence investigations in the Controlled Drug – DEA Standard Operating Procedures Manual and this is supposed to be the single source document. [420]

Another significant difference was in regards to due diligence process. In Document A in the "Identify and Hold Section" of the policy the first paragraph contains the following language:

> *The purpose of the Identify and Hold phase is to identify potentially irregular orders and place a Hold on those orders at the Distribution Center. All orders identified as potentially irregular are labeled "orders of interest" unless determined to be suspicious following the initial due diligence process. Orders of interest are identified by the SOM Analyst while reviewing the PSE Item Review Report (IRR}, the Control IRR, and/or the Florida 5000 Dose Report (FRR) or by warehouse employees reviewing or packing orders for distribution to CVS Stores.*

In Document B the language "or by warehouse employees reviewing or packing orders for distribution to CVS Stores" has been omitted.

Another significant change occurred on the first page in Section 1. – Purpose. The language in Document A is as follows:

> *To detail the three phase approach developed to effectively identify, review and stop potentially irregular orders of PSE or controlled substance drugs identified by the CVS/Caremark Suspicious Order Monitoring (SOM) process, as well as report orders that are deemed to be suspicious.*

The language in Document B for the same section as listed above is as follows:

> *To detail the 3 phase approach developed to effectively review and stop a potentially suspicious order of PSE or Control drug identified by the CVS/Caremark Suspicious Order Monitoring (SOM) process, as well as report orders that are deemed to be suspicious.*

In Document B the word "identify" no longer appears. Further, Document A uses the term "irregular orders" which is changed to "suspicious order" in Document B. The change of these words become more impactful when the use of the term "order of interest" is used in the letter to Mr. Gillen. This change in terminology regarding this area may cause the potential for the reader to draw a different conclusion at which point the order should be reported as suspicious to the DEA.In August, 2013, CVS created "Work Instructions for Suspicious Order Monitoring" [421] and a "DCHuddle Guide."[422] Both of these documents inform employees of CVS's desire to detect and block suspicious orders of controlled substances and other listed chemicals, and they both beg the question of what CVS was doing until August of 2013. Indeed, although CVS claims that its SOM process since at least 2006 relied on Pickers and Packers to detect and stop suspicious orders, the

[420] CVS-MDLT1-00008572-000008635.

[421] CVS-MDLT1-000000299–00000303.

[422] CVS-MDLT1-00003028-00003032.

Huddle Guide appears to be the first written instructions addressing the SOM issue that CVS ever provided to Pickers and Packers.

Other policies and procedures that CVS produced appear to be different versions of documents discussed above, or, in some cases, documents that relate to the new SOM system CVS gradually rolled out in 2014 (the first distribution center going live on March 2, 2014). Due to the limited amount of time that CVS distributed opioids after the introduction of the new SOM system, I have not been asked to opine on this system. I am, however, aware of some of the issues that were raised internally regarding the effectiveness of the new system.[423]

3. Enforcement Actions

In August, 2013 the DEA initiated a regulatory investigation at the CVS Distribution Center in Indiana.[424] After the investigation and after the DEA had outlined some concerns with what it found at CVS, Mark Nicastro, the CVS Indiana Director of Operations, sent correspondence to the DEA. CVS cited the robust "due diligence processes in our pharmacy operations group, which monitor the dispensing of prescriptions across the entire CVS chain to ensure appropriate dispensing by stores" as the "primary contributor to the limited number of suspicious orders identified through our distributor SOM process."[425] The sufficiency of the pharmacy level due diligence component of the CVS SOM program is belied by numerous DEA actions against CVS for the significant due diligence failures in its pharmacy operation, including the following:

a. On October 13, 2010, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve the criminal investigation of unlawful distribution and sales of pseudoephedrine ("PSE") by CVS/pharmacy stores in Southern California and Nevada and a CVS/pharmacy distribution center in Southern California. The CVS Distribution Center in La Habra, California, was in a position to monitor and report excessive PSE sales to the DEA, but failed to do so, in violation of 21 U.S.C. Sec. 830(b) and 21 C.F.R. Sec. 1310.05(a)(1). CVS paid a penalty of $75,000,000 and forfeited $2.6 million in profits for a total payment of $77.6 million.[426]

b. On March 28, 2013, CVS Pharmacy, Inc. and Oklahoma CVS Pharmacy L.L.C. entered into a Settlement Agreement with the United States and the DEA to resolve claims that CVS violated the CSA by : (1) filling prescriptions for certain prescribers whose DEA

[423] Schiavo Depo., 374:23-385:22.

[424] CVS-MDLT1-00008014–00008015.

[425] Nicastro Depo, 203-206; Ex. 42.

[426] *See* Non-Prosecution Agreement found at http://lib.law.virginia.edu/Garrett/corporate-prosecution-registry/agreements/cvs.pdf . *See also* CVS press release announcing Settlement found at https://cvshealth.com/newsroom/press-releases/cvspharmacy-announces-agreements-us-drug-enforcement-administration-and-us-attorneys-offices.

registration numbers were not current or valid; (2) entering and maintaining invalid DEA registration numbers on CVS dispensing records for certain prescriptions, which were at times provided to state prescription drug monitoring programs; and (3) entering and maintaining CVS dispensing records including prescription vial labels that identify a non-prescribing provider as the prescribing provider for certain prescriptions. CVS paid a fine of $11,000,000.[427]

c. On September 2, 2014, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA to resolve claims against CVS for filling (from April 1, 2012 to July 31, 2012) 153 prescriptions at eight (8) different pharmacies, written by the same physician, during a time period during which his Texas Department of Public Safety Controlled Substances registration was expired. CVS paid a $1,912,500 fine.[428]

d. On May 12, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that CVS failed "to fulfill its corresponding responsibility to ensure that CVS dispensed controlled substances only pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 CF.R. §1306.64." The Settlement also covered CVS's "Florida Distribution Center[s] failure to maintain effective controls against the diversion of controlled substances" and failure to timely detect and report suspicious orders of controlled substances. CVS's conduct complained of is set forth in the February 2, 2012 Orders to Show Cause and Immediate Suspension Orders issued to CVS stores 219 and 5195. CVS paid a fine of $22,000,000.[429]

e. On August 7, 2015, CVS Health entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between March 3, 2010 and August, 2015 CVS stores in Rhode Island (1) filled prescriptions with invalid prescriber DEA numbers (knew or should have known in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.04); (2) filled prescriptions for Schedule III controlled substances written by psychiatric nurse practitioners who were not authorized under state law or by terms of their DEA registration to issue such prescriptions, in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.03(a)(1); and (3) entering, creating, or maintaining CVS dispensing records in which the DEA registration numbers of non-prescribing practitioners, were substituted for the DEA registration numbers of prescribing

[427] CVS-MDLT1-000060822–000060829.

[428] CVS-MDLT1-000060907–000060914.

[429] CVS-MDLT1-000060796–000060804.

practitioners, in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1306.24. CVS paid a $450,000 fine.[430]

f. On December 31, 2015, the DEA issued a Letter of Admonition for violations in distributing HCPs at the CVS Indiana distribution center.[431] This DEA finding was the result of the 2013 investigation. The DEA found that CVS violated the Controlled Substances Act because of a:

> "[f]ailure to design and maintain a system to detect suspicious and report suspicious orders for Schedule III-V Controlled Substances as required by Title 21 United States Code (USC) 821, Title 21 USC 823(e)(1), and Title 21 Code of Federal Regulations (CFR) 1301.74(b) in violation of Title 21 USC 842(a)(5) in that CVS failed to detect orders that should have been identified as suspicious for retail locations in Vincennes and Kokomo, Indiana.[432]

g. On February 12, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. In the Settlement, CVS acknowledged that between 2008 and 2012, "certain CVS/pharmacy retail stores in Maryland did dispense certain controlled substances in a manner not fully consistent with their compliance obligations under the CSA…." CVS paid a fine of $8,000,000.[433]

h. On June 30, 2016, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA. The Settlement resolved claims that between 2011 and 2014 CVS pharmacies in Massachusetts had filled hundreds (523) of forged opioid prescriptions. CVS entered into a multi-year compliance agreement and paid a fine of $3,500,000.[434]

i. On July 5, 2017, CVS Pharmacy, Inc. entered into a Settlement Agreement with the United States and the DEA as a result of a DEA investigation showing "an increase in the number of thefts and unexplained losses of Hydrocodone…" at numerous Eastern District of California CVS retail stores. The Settlement resolved claims for the following misconduct: 1) failure to "provide effective controls and procedures to guard against theft and diversion of controlled substances" (*see* 21 C.F.R. §1301.71(a)) and failure to notify the DEA of certain thefts or significant losses of controlled substances

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[430] CVS-MDLT1-000060847–000060855.

[431] CVS-MDLT1-00008014–00008015.

[432] CVS-MDLT1-00008014–00008015.

[433] CVS-MDLT1-000060805–00060811.

[434] CVS-MDLT1-000060872-00060906.

within one business day of the discovery (*see* 21 C.F.R. §1301.74(c)); 2) failure to maintain schedule 3-5 invoices (21 CFR §1304.04(a)); 3) failure to maintain Schedule 3-5 records separate from non-controlled substance records (21 CFR §1304.04 (h)(3)); 4) failure to conduct a Biennial Inventory on one specific day (21 CFR §1304.11(c)); 5) failure to maintain complete and accurate records (21 CFR §1304.21(a)); 6) failure to record the date of acquisition of controlled substances (21 CFR §1304.22(c), 1304.22(a)(2)(iv)); 7) failure to record the amount received on Schedule 3-5 invoices (21 CFR §1304.22(c)); 8) failure to record the amount received and the date received on DEA 222 forms (21 CFR §1305.13(e)); 9) failure to maintain DEA-222 forms (21 CFR §1305. 17(a)); and 10) failure to maintain DEA-222 forms separate from other records (21 CFR §1305. 17(c)). CVS admitted that between April 30, 2011 and April 30, 2013 the retail stores violated their recordkeeping obligations but it denied that the recordkeeping obligations caused any diversion. CVS paid a fine of $5,000,000.[435]

4. <u>Suspicious Orders Reported In CT1 Jurisdictions</u>:[436]

2006: 0

2007: 0

2008: 0

2009: 0

2010: 0

2011: 0

2012: 0

2013: 0

2014: 0

5. <u>Opinions Related to CVS</u>

1. **CVS failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].**

The increase in prescription opioids without any due diligence documentary basis is indicative of a failure to maintain effective control against diversion. The bar graphs identified as

[435] CVS-MDLT1 000060856-000060871.

[436] *CVS RX SERVICES, INC.'S AND CVS INDIANA, L.L.C.'S OBJECTIONS AND RESPONSES TO PLAINTIFFS' (FIRST) COMBINED DISCOVERY REQUESTS TO NATIONAL RETAIL PHARMACY DEFENDANTS (11/30/18). Request Nos. 3-7.*

Figures 39-44 in Schedule II to this report demonstrate a clear increase of distribution of prescription opioids into Cuyahoga County and Summit County by dose, base weight and MME.

2. **CVS failed to *design and operate* a system to identify suspicious orders of controlled substances in violation of the *security requirement* set forth in 21 C.F.R. § 1301.74(b).**

a. **Period #1: 2006 – early to mid- 2009**

From 2006 to early to mid-2009, the CVS SOM program consisted of Pickers and Packers and PDMR ("Viper") Reports.

Pickers and Packers were stationed in the controlled substance cage within the distribution center who would pick and pack controlled substance orders. The Pickers and Packers would identify orders that they believed were simply too large and would notify the Rx Inventory Control manager of the order. Ms. Wilson, a Picker and Packer since 1996, testified that she was guided by a "gut feeling" and then later testified that she used a crude rule of thumb that she learned in 1996 that, according to her, never changed throughout the entire period that CVS distributed HCPs.[437] The evidence indicates that the first formal written policy for the Pickers and Packers was introduced in August, 2013 with two documents: 1) "Work Instructions for Suspicious Order Monitoring" [438] and 2) "DC Huddle Guide."[439] Regardless of the rule used by the Pickers and Packers, the evidence demonstrates that essentially no orders were ever identified by the Pickers and Packers as potentially suspicious and needing investigation. For the Indiana distribution center during the period from 2006 through 2014, Sherri Hinkle was the Rx Inventory Control person that the Pickers and Packers would notify if they believed an order merited investigation.[440] Ms. Hinkle testified that she would be notified and investigate approximately one control drug substance order every six months.[441]

b. Similarly, the Viper report was not an effective SOM process. CVS's own witnesses testified that this report was NOT a report to determine suspicious orders: "But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA."[442] Rather, the Viper Report was an aggregate report that showed shipping versus dispensing

[437] Wilson Depo., 62:8 – 64:6.

[438] CVS-MDLT1-000000299–00000303.

[439] CVS-MDLT1-00003028-00003032.

[440] S. Hinkle Depo., 14:5-15:22; 65:22-66:15; Wilson Depo., 40:21-42:1.

[441] S.Hinkle Depo., 83:23-86:1.

[442] Vernazza Depo., 191:18–21.

to determine whether there was a theft of product.[443] [444] **Period #2 Early to Mid-2009 until March 2014**

1. Item Review Reports[445]

In 2007 CVS hired Buzzeo to help create DEA control drug standard operating procedures. This engagement lead to the manuals identified above as the "CVS Distribution Center Controlled Drug - DEA Standard Operating Procedures (SOPs) Manual." As part of the engagement, in late 2008-early 2009, Buzzeo delivered to CVS an "SOM model … designed to 'pend' an order which may be classified as a 'suspicious' order for DEA reporting purposes."[446] The SOM model consisted of complex multiple logistic regression algorithms and was designed to pend any order with a score of .15 or higher. The IRR was a print-out that consisted of all controlled drug orders for that day that were identified as potentially suspicious by the SOM algorithm. This was a daily report that was run five days per week. As is described in the Due Diligence Conducted section below, CVS only performed due diligence on a small percentage of the orders identified in the IRR as potentially suspicious.

The IRRs had some specific problems that fit within the time periods below but it also had one overarching issue that continued from mid-2009 until March, 2014 – when performing the calculation of whether the order was suspicious, the IRRs did not consider orders delivered to CVS pharmacies by outside vendors.[447] CVS had full access to every order its pharmacies placed to outside vendors but did not incorporate this information in its SOM system. Maintenance of effective controls requires CVS to utilize all relevant transaction information. Not surprisingly, the VIPER reports which are used as inventory tools and to gauge whether there is a loss of product from theft automatically incorporates outside vendor information. [448]
The outside vendor issue was not rectified until the new AGI SOM program was implemented in 2014. As late as January of 2013, CVS was analyzing the potential risks of not tracking orders that its pharmacies placed to outside vendors and concluded that it needed to due to the "DEA 'Know Your Customer' requirements."[449] CVS recognized that in order for the "dispensing data in the algorithm to be useful, we must account for all controlled substances ordered."[450] In fact, a

[443] Burtner Depo., 384:12–21.

[444] Dugger Depo., 104:12–22.

[445] During this period the IRR was the primary SOM process used by CVS. However, CVS also continued to use the Pickers and Packers and PDMR Viper reports in conjunction with the IRR.

[446] *See* Cegedim Dendrite Compliance Solutions Powered by BuzzeoPDMA "Descriptive Over Document: Cegedim Dendrice Suspicious Order Monitoring (SOM) Model" Version 1.0 – December 2008. CVSMDLT1-000123386–000123392).

[447] Burtner Depo., 284:21 – 285-20.

[448] Burtner Depo., 382:20 -387:17.

[449] CVS-MDLT1-000103328, at 28.

[450] CVS-MDLT1-000103328.

CVS pharmacy lost 68,000 hydrocodone pills and then refilled its hydrocodone supply by calling outside vendors instead of placing orders through the CVS distribution centers.[451] Most troubling, according to CVS, in the event that CVS detected an order to an outside vendor which CVS identified "as an order deviating from normal size, frequency, and/or buying pattern and deemed to not be for legitimate purposes or are at risk of being diverted [those orders] are **not** required to be reported to the DEA."[452]

a. Early to Mid-2009 through March, 2011

i. Changing the Algorithm Triggering Score

From early to mid-2009 through March, 2011, the IRR (for the entire country) was being reviewed by Henry "John" Mortelliti. Mortelliti was the first individual to begin review of the new IRR and he worked in loss prevention at the Lumberton distribution center in New Jersey. The SOM algorithm delivered in December 2008 and implemented in early 2009 was designed to pend an order with a score of 0.15 or higher. In July, 2009 CVS reported to Buzzeo that the SOM model was pending a large number of orders that CVS believed were "not suspicious on their face" and it requested that the model be changed. As a result revised coefficients for the algorithm were delivered to CVS on August 27, 2009and the pend score of .15 remained the same.[453] [454]. Between June, 2010 and August, 2010 Mortelliti adjusted the IRR pend score from .15 to .65.[455] On February 8, 2011 a completely retuned SOM algorithm was delivered to CVS with another set of co-efficients. The February, 2011 changes returned the pend score to .15.[456] However, a review of IRRs from February and March of 2011 shows that the pend score was .65. In fact, an IRR from as early as February 20, 2011, nine days after the consultant returned the model and returned the pend score to .15, demonstrates that the score at that point was already returned by CVS to .65.[457] Further, I have been informed that no documents have been produced that indicate why, after the model was retuned by the consultants and the pend score returned to .15, CVS again changed the pend score to .65.

ii. All Flagged HCP Orders That Appear On The IRR Are Sent Out To Analysts For Additional Specialized Investigation

[451] CVS-MDLT1-000103327.

[452] CVS-MDLT1-000078060-000078069, at 78068 (emphasis added).

[453] CVS-MDLT1-000109623-000109625.

[454] CVS-MDLT1-00114642-00114652.

[455] Mortelliti Depo. Exs. 612, 614, 615.

[456] CVS-MDLT1-24494; 24495-24499; P. Hinkle Depo., pp. 194-214.

[457] CVS-MDLT1-000100851-000100864.

Mortelliti testified that while he was reviewing the IRR, every HCP order that appeared on the IRR was referred out for additional investigation which he believed was necessary.[458] Although Mortelliti testified that he felt it was necessary for all HCP flagged orders to be sent out for additional investigation, he has no idea what due diligence was actually performed. It is my opinion that all HCP orders that were flagged on the IRR merited additional investigation beyond just reviewing the information on the IRR. Significant evidence exists that calls into question the accuracy of Mortelliti's statement. First, Mortelliti testified that he would contact the loss prevention manager and the pharmacy manager of the distribution centers to freeze all orders that were flagged on the IRR.[459] However, Dugger, the Indiana loss prevention manager, told the DEA that he never received a call from Mortelliti about the IRR.[460] Second, during this time period Mortelliti testified that the Field Viper analysts were the individuals reviewing every order of HCP that flagged on the IRR. However, I have been informed that the only documents that indicate any investigation that was ever done on individual orders by these types of analysts during this time period are the IRR Recaps and the IRR Recaps directly contradict Mortelliti's testimony. *ee* section on IRR Recaps). Mortelli was questioned during his deposition as to whether he was able to find documentation that supported his position that he sent all IRR flagged orders of HCP out for additional investigation. He unequivocally testified that he tried to find documents that supported his story that he sent these flagged orders out for additional investigation but he was unable to find any supporting documents.[461]

iii. Algorithm Not Functioning Correctly – Loses Historical Data – Active Ingredient

In October of 2010 it was discovered that the algorithm was not functioning properly. Because the algorithm monitored orders by drug and not active ingredient, any change in how the drug was identified would cause the historical data to be lost. In a business description document requesting resources to change the model, Mortelliti wrote in October of 2010, that the algorithm model lost historical data and caused CVS to not be compliant with DEA expectations.[462] The loss of the historical data caused the algorithm to not function properly. Although it is unclear when the model was fixed, a business request update of April 25, 2011 indicated that the problem was still not fixed and it had a finish date of December 31, 2011.[463]

b. March/April, 2011 to December, 2013

In March/April, 2011 CVS moved the IRR review process to the Knoxville, Tennessee distribution center. At this point, the active ingredient issue was still not fixed and the IRRs were still missing historical data. From March, 2011 until early 2012, the IRR review for the entire

[458] Mortelliti Depo., 367:1–14.

[459] Mortelliti Depo., 57:16 – 58:12.

[460] Mortelliti Depo., 58:17 – 62:18; Exh. 135.

[461] Mortelliti Depo., 220:7 – 221:22.

[462] Mortelliti Depo., 129:11 – 131:11, Ex, 16; Vernazza Depo., 400 – 455.

[463] Mortelliti Depo., 177:9 – 186:2.

country was centralized in Knoxville. In early 2012, Aaron Burtner began reviewing IRRs at the Indiana distribution center.[464] During this period, the evidence indicates that the IRRs would consist of hundreds of flagged orders with some IRRs having over 1,000 orders. All orders listed on the IRR were identified by the computer algorithm as potentially suspicious and should have had additional investigation. The evidence indicates that during this period, very few orders that were identified on the IRR as potentially suspicious were investigated beyond the IRR. (*See* Due Diligence Conducted).

2. Due Diligence Conducted

Due diligence, as it relates to CVS's SOM program, can be broken down into two distinct subparts: i) What tools were available to conduct due diligence; and ii) What due diligence was actually performed based on the evidence produced by CVS. CVS might claim that reviewing the information contained within the four corners of the IRR constitutes due diligence, but little information exists on the IRR that is probative of why an order is suspicious and represents a threat of diversion. The CVS SOM program was dependent upon all flagged orders receiving a comprehensive due diligence investigation. This was acknowledged by Mortelliti when he testified that he referred all HCP flagged orders out for additional investigation. The evidence demonstrates that CVS conducted very little effective due diligence.

i) What tools were available to conduct due diligence

Viper Report It appears that before 2012, the Viper report was the only due diligence tool available. As outlined above, Viper was really just an inventory control, theft detection system and was not designed or operated to "produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA."[465] b. Microstrategy

Microstrategy was implemented as a SOM tool in February, 2012.[466] This database was the primary SOM tool an analyst could use if an investigation of an order beyond the IRR was done. Microstrategy provided an analyst with the information necessary to do appropriate due diligence: patient ID number, if a doctor is prescribing an inordinate amount, how the drugs were paid for, distance patients traveled to fill the prescriptions, quantity dispensed, dispensing data, information on the pharmacy, information on the patient, [467] and outside vendor deliveries of the same drugs to the stores. [468]

c. Store metrics

[464]In September, 2012 the IRR review is centralized again and now the entire country is being reviewed at the Indiana distribution center.

[465] Vernazza Depo., 191:18-21.

[466] Burtner Depo., 379:4-13.

[467] Burtner Depo., 385: 6–18; 396:23–397:17; Helfrich Depo., 18:4–19:8; 176:3–12.

[468] Burtner Depo., 284-6: 285:9.

In December, 2012, CVS introduced a new tool for due diligence called Store Metrics that produced a report called "Store Statistics for SOM Order Review." Store Metrics contained much of the same information (top doctors, top patients, volume, distance traveled, patient population, payment method)[469] but formatted into an easily readable report. The Store Metrics report was the primary tool for doing investigations, but the report used stale data that by July 2013 was over one year old and made the report "irrelevant and pointless."[470]

ii) *What due diligence was actually performed based on the available evidence:* All of the evidence indicates that CVS performed due diligence on very few orders that were flagged by the IRR system. Mortelliti testified that while he was reviewing IRRs from mid-2009 until March of 2011 he sent every flagged orders of HCP out for additional investigation but as addressed above and below that is belied by the evidence. Further, the evidence affirmatively demonstrates that from January, 2011 until the new SOM system was implemented in March,2014, very few of the orders flagged on the IRR as suspicious were ever investigated. This is established by 1) the IRR recaps that list the few flagged orders that received a due diligence investigation; 2) the time studies that demonstrate how few orders were actually investigated; and 3) the testimony of Gary Millikan who indicated that he investigated 5% or less of the IRR flagged orders; and 4) the testimony of Shauna Helfrich and Kelly Baker who both indicated that they did not investigate all of the flagged orders and they had no idea how many they would actually investigate.

a. *IRR Recaps*: According to CVS policy and testimony, anytime an order received due diligence beyond simply reviewing the IRR, that review was documented on the IRR Recap.[471] Review of the IRR Recap Reports shows that few orders actually received additional investigation. The IRR Recap Report from January, 2011 to June, 2012 shows that only one flagged HCP order placed by a pharmacy in CT1 was investigated.[472] The IRR Recap Report from February 6, 2013 to December 30, 2013 shows that only one flagged HCP order placed by a pharmacy in CT1 was investigated.[473] **In other words, over a 28-month period, during the height of the opioid crisis, CVS undertook two investigations of HCP orders in CT1.** Additionally, an IRR

[469] Burtner Depo., 311:2-23.

[470] Baker Depo., 259:16–262:19; Ex. 27;; Ex. 29.

[471] Burtner Depo. , 404: 24–405:10; 474:23–475:8. P. Hinkle Depo., 130:8 - 131:1.

[472] Burtner Depo., 488:6–490:4; Ex. 441.

[473] Burtner Depo., 485:2–487:1; Ex. 440.

Recap from January 2, 2014 to February 11, 2014 demonstrated that one CT1 store had an order investigated during this time period.[474] The IRR Recaps also contradict Mortelliti's claim that he referred all HCP orders for additional investigation. Mortelliti was reviewing IRRs during the first three months that the recaps are available (January, February, March of 2011). I have been informed that during that time period, 37 HCP orders for CT1 stores were flagged on the IRR and not one of those orders appears on the IRR Recap as receiving additional investigation.

b. *Time Studies:* Mr. Burtner, who began reviewing IRRs in February, 2012 and was subsequently named the SOM Manager, created various time studies as part of his job. The time studies were intended to track a typical day. During the time Burtner created the time studies he was reviewing the IRR for half the country – five distribution centers. Over twelve days in 2012, the time studies indicate Burtner performed an investigation beyond the IRR on zero (0) orders on eight (8) separate days; one (1) order on two (2) separate days; two (2) orders on one (1) day; and three (3) orders on one (1) day. In other words, for one half of the country over a period covering twelve days ranging from June 14, 2012 to September 6, 2012, CVS investigated a total of seven control substance orders.[475]

c. *Less Than 5%:* Gary Millikan was the operations manager at the Indiana distribution center from 1998 until 2010, and the production manager until he retired in June, 2012He also was the Indiana distribution center DEA Compliance Coordinator from 2006 through his retirement in June, 2012. .[476] Because the distribution center was so short-staffed in the SOM department, he came back to work part-time in August, 2013 and he started reviewing IRRs. Mr. Millikan admitted during his deposition that he did due diligence on less than 5% of the suspicious orders flagged on the IRR.[477]

d. *No Idea How Few Orders Were Investigated:* Shauna Helfrich, an IRR analyst, testified that she does not remember how many flagged orders

[474] Helfrich Depo.,142:17–143:22; Ex. 14.

[475] Burtner Depo., 340–371; 505; Ex. 500.

[476] Millikan Depo., 32:20 – 33:11.

[477] Millikan Depo., 213:9 – 214:12.

on an IRR she did additional due diligence on. Despite repeated questions on her due diligence efforts, Ms. Helfrich was not able to even estimate or give a percentage of how many flagged orders on which she did due diligence. She had absolutely no memory or idea of the orders on which she did due diligence. [478] Kelly Baker, another IRR analyst, also could not remember how many flagged orders on an IRR she did due diligence or a deep dive on. He merely remembers one example of a deep dive that he did and that is it. Furthermore, Mr. Baker did not dispute Gary Millikan's testimony that he did a deep dive on about five percent of the orders on an IRR.[479]

iii) *A Due Diligence Investigation Should Have Been Conducted On All HCP Orders Flagged On The IRR As Suspicious:* As I referenced above, it is my opinion that all orders that flagged on the IRR should have received additional investigation. This would include all orders that flagged on the IRR as a result of violating CVS's Maximum Cutoff Volume and Maximum Cutoff Ratio; two thresholds that were established in October, 2012.[480] I agree with Mr. Mortelliti's testimony that all flagged orders of HCP needed to be referred out for additional investigation.[481] Additional investigation could include review of patient profiles such as the age, distance traveled, and method of payment; review of ratios of HCP purchases to other controlled substances; review of other drugs purchased that consist of a drug cocktail; review or comparison to like stores; review of prescribing physician profiles; and total amount of a drug purchased by the pharmacy. As is clear, none of this information is shown on the IRR.[482]

The implications of the failure to perform additional investigation on orders flagged on the IRR cannot be overstated. As referenced above, from January, 2011 to June, 2012 one flagged HCP order placed by a pharmacy in CT1 was investigated.[483] Similarly, from February 6, 2013 to December 30, 2013 one flagged HCP order placed by a pharmacy in CT1 was investigated. Combined, two orders were investigated over an 18

[478] Helfrich Depo., 105:5-107:24.

[479] Baker Depo., 102:9-103:6; 165:14-166:22.

[480] CVS-MDLT1-00055836-00055838.

[481] Mortelliti Depo., 367:4-22; 368:22-369:2.

[482] Millikan Depo., 230:24-232:7. Additionally, total purchased is not shown on the IRR since the IRR does not include outside vendor orders.

[483] Burtner Depo., 488:6–490:4; Ex. 441.

month period. As referenced above, 37 HCP orders flagged on the IRR from January, 2011 through March, 2011 (a 3 month period). This is a large number of orders to simply ignore. These numbers must be evaluated with the understanding that CVS had also artificially reduced the number of orders flagging by increasing the pend score from .15 to .65.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by CVS has been inadequate. While CVS has employed different due diligence programs over the years, a review of those programs in practice make clear that for all practical purposes, CVS's due diligence efforts have fallen short of what is required.

3. **Reporting Requirement**.

CVS timely reported zero suspicious orders from 2006 to September 30, 2014. Further, using any of the methodologies as described in the Expert Report of Craig McCann, it is apparent CVS failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.[484]

4. **Shipping Requirement.**

CVS claims that when it "determines that an order for a controlled substance is suspicious, its policy is and has been to decline to ship the order and to report the order to the DEA."[485]

[484] *See* Section III, "Identifying Suspicious Orders Distributed in CT1."
[485] *CVS'S WRITTEN RESPONSES TO TOPICS 8, 9, 12, 13 AND 14 OF PLAINTIFFS' AMENDED SECOND NOTICE OF DEPOSITION PURSUANT TO RULE 30(b)(6), Response No. 14.*

E. Walgreens Boots Alliance

Distribution Centers:

During the relevant time period Walgreens Boots Alliance, Inc. ("Walgreens") had 13 Distribution Centers ("DCs") that handled controlled substances. Three of those DCs handled schedule 2 controlled substances (Jupiter, Florida; Perrysburg, Ohio; and Woodland, California).[486] According to Walgreens Transactional Data, Walgreens distributed prescription opioids to the CT1 jurisdictions through at least five of its Distribution Centers:[487]

- Perrysburg, Ohio Distribution Center (DEA # RW0294493) from at least May 2003 through March 2013;
- Mt. Vernon, Illinois Distribution Center from (DEA # RW0152467) February 2013 through April 2014;
- Jupiter, Florida Distribution Center (DEA # RW0277752) from at least September 2002 through January 2007;
- Bethlehem, Pennsylvania Distribution Center (DEA # RW0161872) from at least August 2002 through May 2003; and
- Orlando, Florida Distribution Center (DEA # RW0155994) from at least August 2002 through September 2002.

Transactional Data Disclosed:

Date range: 1996 through 2014[488]

Volume:

Cuyahoga[489]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	[redacted]		
Hydrocodone			

Summit[490]	**Total Dosage**	**MME**	**Base Weight**
Oxycodone	[redacted]		
Hydrocodone			

[486] *See* WAGMDL00659801 at WAGMDL000659817. *See also* WAGFLDEA00000117 (listing all three CII facilities)

[487] *See* WAGMDL00293631; WAGMDL00490979; WAGMDL00773926; ABDCMDL00170319; and MNK-T1_0005986422 at MNK-T1 0005986423.

[488] *See* WAGMDL00293631; WAGMDL00490979; and WAGMDL00773926.

[489] *See* Expert Report of Craig J. McCann, Ph.D, CFA, App. 10, p. 226.

[490] *Id*. at p. 856.

1. Court ordered SOMS Discovery Disclosure

- *Walgreens Boots Alliance, Inc.'s Objections and Responses to Plaintiffs' First Set of Interrogatories (6/21/2018);*
- *Walgreen Co. And Walgreen Eastern Co.'s Amended Objections and Responses to Plaintiffs'*
- *First Set of Interrogatories (10/3/2018);*
- *Walgreen Co. and Walgreen Eastern Co's Responses to Plaintiffs' "(First) Combined Discovery Requests" (11/30/2018);*
- *Walgreen Co. and Walgreen Eastern Co's Supplemental Responses to Plaintiffs' "(First) Combined Discovery Requests" (12/21/2018);*
- *Walgreen Co. and Walgreen Eastern Co's Objections and Responses to Plaintiffs' First Notice of Deposition Pursuant to Rule 30(b)(6) Topic 1(O) and Second Notice of Deposition Pursuant to Rule 30(b)(6) Topics 2 (A)-(J), 9, 10, 11, 13, 14 and 15 (1/17/2019);*
- *Walgreen Co. and Walgreen Eastern Co's Second Supplemental Responses to Plaintiffs' "(First) Combined Discovery Requests" (2/19/2019);*
- *Walgreen Co. And Walgreen Eastern Co.'s Second Amended Objections and Responses to Plaintiffs' First Set of Interrogatories (3/4/2019).*

2. SOMS Corporate Policy Disclosed

Walgreens's various SOM Programs are described in my opinions, set forth below in other areas of this report.

3. Enforcement Actions

In May 2006, the DEA sent Walgreens a Letter of Admonition citing Walgreens for recordkeeping inadequacies and security deficiencies at its Perrysburg Distribution Center. Specifically, the DEA found that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient."[491]

In April 2012, the DEA served a Subpoena to one of Walgreens's Schedule 2 controlled substance distribution centers, the Jupiter Distribution Center, requesting, among other things, all controlled substance SOPs, communications about controlled substances, and customer due

[491] WAGMDL00709510.

diligence files for 14 Walgreens stores, and also served a Warrant of Inspection on the Jupiter Distribution Center, authorizing seizure, among other things, all records related to distribution of controlled substances.[492]

After reviewing the materials provided by Walgreens in response to the April 2012 subpoenas, on September 13, 2012, the DEA issued an Order to Show Cause (OTCS) and Immediate Suspension of Registration (ISO) to Walgreens on the basis that the Jupiter Distribution Center constituted "an imminent danger to the public health and safety" and ordered that Jupiter controlled substance vault be sealed.[493] The DEA alleged that Walgreens's Jupiter DC failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies. Further, the DEA alleged that Walgreens's failure to sufficiently report suspicious orders was a systemic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone. The allegations in the OTSC and ISO were exacerbated by the fact that over a year earlier, on April 7, 2011, Walgreens had entered into a prior Settlement Agreement with DEA regarding allegations of non-compliance with the Controlled Substance Act wherein Walgreens had agreed to "maintain a compliance program to detect and prevent diversion of controlled substances."[494]

In February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg Distribution Center.[495] Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC.[496] Within weeks of receiving the six subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances from the Perrysburg facility" in order to "eliminate any immediate need for further DEA administrative action" regarding the Perrysburg facility.[497]

On June 11, 2013 Walgreens entered into a Settlement and Memorandum of Agreement ("MOA") with the DEA to resolve outstanding allegations involving the Walgreens Distribution Centers and pending actions concerning six Walgreens retail pharmacies located in Florida. Walgreens agreed to pay $80 million in civil penalties, the largest settlement in DEA history at that time, to resolve the DEA's claims that Walgreens negligently allowed controlled substances, including oxycodone and other prescription painkillers, to be diverted into the black

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[492] WAGMDL00777158; CAH_MDL2804_01431074.

[493] *See* Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, "Walgreens 2013 MOA") (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), ["Jupiter Show Cause Order"]).

[494] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387975.

[495] WAGMDL00493697; WAGMDL00493694.

[496] WAGMDL00477975; WAGMDL00358471.

[497] WAGMDL00674280.

market.[498] In addition to the $80 million civil penalty, Walgreens agreed to surrender its Jupiter DC's registration to distribute or dispense controlled substances listed in Schedules II – V for two years from issuance of the Jupiter ISO, ending in 2014. As part of the MOA, Walgreens admitted that Walgreens's "suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007."

4. **Due Diligence Conducted:**

Due Diligence, as discussed in more detail in other areas within this report, relates to the KYC process and specific investigations related to potential suspicious orders in an effort to determine if said orders may be shipped. Walgreens conducted very limited and irregular due diligence prior to the formation of the Pharmaceutical Integrity Department in late 2012/beginning of 2013. For example, limited pre-2012 emails produced by Walgreens reveal that the "warehouse" (Walgreens DC) would call stores to inquire about large orders, but those orders would be cleared if the store confirmed that they were intentionally placed.[499] Even after the creation of the Pharmaceutical Integrity Department, Walgreens did little due diligence and did not keep complete records of any due diligence performed outside of a relatively small number of emails beginning in 2012[500] and sparse database notations about limited orders in and after 2013.[501] Walgreens failed to produce any due diligence records pre-dating 2011. Walgreens's failure to retain historical records and failure to incorporate historical due diligence information into its SOMs program is problematic because an important aspect of every due diligence review should always be an examination of the historical of the customer who placed the flagged order. Without such information, one cannot fully evaluate trends over time or make fully informed decisions about whether or not orders of controlled substances are likely to be diverted into illicit channels.

Walgreens claims that it engaged in "a variety of practices" for conducting due diligence on potentially suspicious orders over time.[502] One of the practices Walgreens specifically points to is that from "time to time, the distribution centers' function managers also sought input from personnel in Rx Inventory, who, upon request, reviewed sales history, order history, and item movement for individual stores, to determine whether orders were in line with a store's history or were unusual."[503] Walgreens points to two documents and the testimony of two individuals, Rx

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[498] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974).

[499] *See, e.g.,* WAGFLDEA00000459.

[500] *See e.g.* WAGMDL00107532.

[501] *See* WAGMDL00400358 (ohio_cso_override_history_updated_drug_list.xlsx) (containing limited to information from Sept 2013 – Sept 2018); WAGMDL00400360 (ohio_flagged_orders.xlsx) (only shows certain flagged orders from Sept 2016 – Sept 2018).

[502] Walgreens Second Supplemental Responses to Combined discovery, Request No. 7.

[503] *Id*.

Inventory manager, Barbara Martin and Perrysburg Distribution Center CII Function Manager, Deborah Bish, to support this claim.

The first document Walgreens cites is an email chain dated January 10, 2011, between the Jupiter DC CII Function Manager, Kristine Atwell, and Rx Inventory manager, Barbara Martin. In the email chain, the Ms. Atwell expresses concern that she has "several stores that are ordering huge quantities of 682971 on a regular basis."[504] The item Ms. Atwell refers to as "682971" is Walgreens Inventory Checker ("WIC") number for 30 mg oxycodone.[505] Ms. Atwell goes on to state, "I feel that the store needs to justify the large order quantity. Three stores that come to mind are #7298, #3836 and #5018."[506] Ms. Martin responds and provides sales history for two of the three stores specifically mentioned, notes that the third store's system was down, and states, "You can contact the store for more information if necessary. These sales are quite high compared to other non-Florida stores." Apparently unsatisfied with Ms. Martin's response, Ms. Atwell replies stating, "I ran a query to see how many bottles we have sent to store #3836 and we have shipped them 3271 bottles between 12/1/10 and 1/10/11. I don't know how they can even house this many bottle to be honest. How do we go about checking the validity of these orders?" Ms. Martin responds identifying the district pharmacy supervisor's cell phone number and telling Ms. Atwell that he "may be able to shed some light on the subject."

The second document cited by Walgreens is a continuation of the email chain which resumed the following day. Ms. Atwell asks for information regarding the store #3836, the store that Ms. Martin could not access the previous day. Ms. Martin responded relaying that the store had average weekly sales of 36,200 dosage units which was equal to 362 bottles per week and noting, "have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)."[507]

Despite having raised these concerns from the DC to a supervisor at corporate headquarters, it appears that this exchange is the full extent of the "due diligence" performed on the "huge quantities" of oxycodone identified by Walgreens's DC personnel and was typical of Walgreens's due diligence process.[508] There is no evidence of any actual due diligence beyond this facially insufficient email exchange. Further, despite the fact that questions had been raised about this store #3836's ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another [redacted] dosage units of 30 milligram oxycodone to the same pharmacy.[509] This one store, located in Port Richey, Florida, a town of less than 3000 people in a county with a population of only approximately [redacted], went from [redacted] units of oxycodone

[504] Martin Dep. Ex. 30 (WAGFLDEA00000846).

[505] WAGMDL00436802.

[506] B. Martin Dep. Ex. 30 (WAGFLDEA00000846).

[507] WAGFLDEA00000852.

[508] B. Martin Deposition at 337:16 to 338:19; Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658.

[509] Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658.

in 2009 to [redacted] units of oxycodone in 2011.[510] Walgreens also cites to the testimony of Ms. Martin as supportive of this type of due diligence, however, in her deposition, Ms. Martin, the Walgreens inventory manager responsible for performing due diligence on this order, stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone.[511] She further testified that she was not near that store, did not have access to the store's prescriptions or patient information, and couldn't take any "direct action."[512] It is not surprising that approximately 18 months after this email exchange, store #3836 was one of the stores for which Walgreens agreed to surrender DEA registration.[513] Ms. Martin's response confirms that Walgreens was not performing the required and appropriate due diligence.

Walgreens also cites to the testimony of Deborah Bish, the CII function manager at Walgreens's Perrysburg DC. However, Ms. Bish could only recall one instance in the entire time she was a the CII Function Manager, from October 2002 to present, that she contacted Ms. Martin regarding a questionable order.[514] Further, Ms. Bish testified that the one time she elevated an order to Ms. Martin, Ms. Martin cleared the order to be delivered.[515]

This type of inadequate due diligence evidences Walgreens's systemic failure to protect against diversion. Walgreens, when notified by its own employees of the presence of indicators of the pending threat of diversion, took no action to prevent diversion. This failure is a total disregard of the maintenance of effective controls against diversion.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by Walgreens has generally been substandard at best. Walgreens practice of attempting to catch and correct ordering errors at the distribution center level is and inventory management program and does not satisfy Walgreens due diligence obligations. As noted below, Walgreens admits that they performed no pre-shipment or post-shipment due diligence on any orders that were flagged by their Rigid Formula Reports. Additionally, even when Walgreens began to cut orders that exceeded their "tolerance," "frequency," or "ceilings," their policies did not call for appropriate due diligence to be performed on such orders and did not specify what constituted appropriate due diligence. While I am aware that Walgreens claims it conducted due diligence via email, phone calls, or other undocumented means, my review of the materials as referenced herein belie those claims, indicate that such actions rarely occurred, and that even when they did occur, they fell short of what is required.

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[510] Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387656-58; B. Martin Deposition at 343:22 to 351:17.

[511] B. Martin Deposition at 349:7 to 350:12.

[512] B. Martin Deposition at 337:16 to 338:19.

[513] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658

[514] D. Bish Deposition at 28:4-10; 89:15 to 91-10; D. Bish Deposition Exhibit 3.

[515] D. Bish Deposition at 89:15 to 91-10.

5. Suspicious Orders Reported In CT1 Jurisdictions

	Pre-Shipment Reporting	Post-Shipment Reporting
2006	None	Rigid Formula Reports (Customer Grouping Formula)
2007	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2008	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2009	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2010	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2011	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2012	None	Rigid Formula Reports (Chemical Handlers Manual Appendix E-3)
2013	None	None
2014	None	None
2015	None	None
2016	None	None
2017	None	None
2018	None	None

Walgreens has testified that, other than the Rigid Formula Reports, it could not "identify" any reports to the DEA of "suspicious orders of opioids" from 2006-2014 in CT1 despite a "diligent search".[516] Walgreens testified no due diligence was conducted on the orders listed in the Rigid Formula Reports.[517]

6. Opinions Related to Walgreens

1. **Walgreens failed to *maintain effective control* against diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970].**

[516] *See* Walgreens Second Supplemental Responses to Combined Discovery Requests at Requests 3 and 4.

[517] *See* E. Bratton Errata.

The bar graphs identified as Figures 45-56 in Schedule II to this report demonstrate a clear escalation of prescription opioids into Cuyahoga County and Summit County by dose, base weight and MME.The massive increase in prescription opioids without a documented basis is indicative of a failure to maintain effective control.

Walgreens's also knew opioids it distributed in Florida were migrating into Ohio. Because Walgreens failed to maintain many pre-2012 documents outside of those produced to the DEA during the Jupiter DC investigation, many of the pre-2012 documents Walgreens produced relate to Walgreens distribution in Florida. This information is highly relevant to CT1, however, because not only does the evidence show that Walgreens's distribution failures were "systemic", as noted by the DEA in the 2013 MOA, but the evidence further shows that Walgreens knew and/or should have known that the high-volume Florida prescriptions were traveling out of state, including to Ohio. For example, Pharmacy managers in Florida alerted their supervisors and the distribution center that they were ordering 55+ bottles a week (where 30 bottles was an admitted red flag) and that many of the prescriptions were coming from out of state.[518] Walgreens was well familiar with the "Florida migration" phenomenon, in which prescription opioids were being dispensed in Florida and transported north to states include Ohio,[519] and knew that ''Interstate 95 has been renamed the Oxycodone Express because of the brisk travel of people from Kentucky, Tennessee, [and] Ohio to South Florida to obtain medications.''[520] When the DEA issued Orders to Show Cause to Walgreens's Jupiter Distribution Center and six Florida Walgreens pharmacies, the DEA specifically noted likely migration to Ohio.[521]

2. Walgreens failed to *design and operate a system to identify suspicious orders* of controlled substances in violation of the security requirement set forth in 21 C.F.R. § 1301.74(b).

Walgreens employed a number of limited and disjointed SOMS programs during overlapping time periods, none of which fulfilled Walgreens's duties under the CSA. Walgreens's documentation of many of these programs is minimal and, before 2011/2012, there is little evidence that Walgreens took any steps to more than nominally comply with the CSA's requirements. Walgreens's failures to design and operate an effective SOM program are especially problematic because Walgreens, as a self-distributor, had limitless information about its customers available to it at times. As Walgreens admits, Walgreens's distribution "customers" are the "individual Walgreens pharmac[ies]" and Walgreens had the ability to conduct "data mining…

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[518] WAGFLDEA00000459

[519] WAGMDL00289068, at 289153-154.

[520] WAGMDL00037521..

[521] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387727, WAGMDL00387760, WAGMDL00387762, WAGMDL00387833, WAGMDL00387866, WAGMDL00387868, WAGMDL00387876, and WAGMDL00387941 (detailing suspicious Florida dispensing to Ohio customers), and at WAGMDL00387753 (describing evidence that "many individuals from Ohio … have travelled by carloads to … Florida to obtain prescriptions for oxycodone….").

across retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive…." [522]

Walgreens Ordering System for Prescription Opioids

Because Walgreens self-distributed,[523] only distributing controlled substances to its own pharmacies, Walgreens's distribution and pharmacy ordering operations were highly integrated. Walgreens provided stores with suggested orders for controlled substances, with amounts based on the stores' previous orders for that drug. As part of its new SOM program, which was not fully implemented until late 2012/early 2013, Walgreens began to more strictly control the recommended orders and implemented ceilings which more strictly limited stores' ability to exceed the recommended order amounts. As summarized by one of Walgreens's Pharmaceutical Integrity Managers in August 2013:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override …. The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.[524]

As discussed below, the record confirms that Walgreens's SOM program permitted excess distribution of prescription opioids to Walgreens's pharmacies through at least 2013 without any comprehensive limit or review.

Walgreens's Outside Distributors Flagged Walgreens Stores for SOM Violations and Relied on Walgreens for Due Diligence

In addition to self-distributing, Walgreens knew its pharmacies also received shipments of opioids from outside distributors, including Cardinal, Anda, and AmerisourceBergen. Walgreens not only had access to data regarding the amount of opioids the Walgreens pharmacies were receiving from the outside distributors, but Walgreens knew that the outside distributors relied on Walgreens for some portion of the outside distributors' due diligence.[525] Additionally, Walgreens knew that its outside distributors were flagging its own pharmacies for making suspicious orders

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[522] WAGMDL00757776.

[523] During the time during which Walgreens was self-distributing, Walgreens stores also received shipments of controlled substance from outside vendors at various times, including from Cardinal Health, AmerisourceBergen, and Anda.

[524] WAGMDL00021425.

[525] *See, e.g.* WAGMDL00302958; WAGMDL00246284; WAGMDL00242055; WAGMDL00032660.

for prescription opioids,[526] and yet continued to self-distribute to those pharmacies without reporting any of those pharmacies' orders as suspicious.

a. *RX Questionable Order Quantity (2006 – Present):*

In 2006 Walgreens instituted the Questionable Order Quantity policy, which purported to establish procedures for verifying questionable store order quantities for prescription items.[527] This policy instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. Once all orders were reviewed for accuracy, they were to be processed by the DC. From 2006 to 2010 this policy made no mention of reporting suspicious orders. In 2010 the policy was updated to include language that suspicious store orders and inquiries would be handled through the Corporate Office Internal Audit Department and noted that suspicious orders would be reported to the DEA within 3 days, however the policy gave no specifics as to how or by whom such orders would be reported.[528] There is further no evidence in the record that the Internal Audit department had any involvement in reporting suspicious orders. For example, the Chief Audit Executive at Walgreens could not recall any audit department responsibility concerning specific suspicious orders.[529] This policy was updated again in October 2013 to state that Walgreens Strategic Inventory Management System will stop what would be considered suspicious controlled drug orders from being released for picking.[530]

Walgreens was unable to locate any policies or procedures that Walgreens's DC personnel used to identify suspicious or abnormal orders.[531] Walgreens admits, however, that DCs do not have the ability to detect trends in local markets.[532] Similarly, Walgreens could not locate any training materials related to this procedure[533] and Walgreens DC personnel did not recall receiving any training related to orders deviating from a normal pattern.[534] Further, according to Walgreens's DC personnel there were no guidelines for determining what constituted an abnormal or suspicious quantity, but generally anything in the triple digits would be flagged.[535] This meant that a store had to order 100 or more 100 count bottles oxycodone or hydrocodone (10,000 dosages units)

[526] *See, e.g.* WAGMDL00302958; WAGMDL00246284; WAGMDL00242055.

[527] WAGMDL00757788.

[528] WAGMDL00751821 at WAGMDL00751822..

[529] *See e.g.* Deposition of C. Domzalski, at 165.

[530] WAGMDL00749381.

[531] *See* E. Bratton Deposition at 138:4-16; 142:18 to 143:2; 50:4 to 51:14.

[532] WAGMDL00659801, at WAGMDL00659817.

[533] *Id*. at 100:21 to 101:4.

[534] See D. Bish Deposition at 72:22 to 73:23.

[535] See D. Bish Deposition at 80:16 to 81:7.

before an order would be flagged.[536] Walgreens was also unable to produce any files documenting any due diligence related to this procedure.[537]

The creator of the order quantity query at Walgreens testified the query was not created for the purpose of identifying suspicious controlled substances orders, but was that it utilized a single number to identify unusually large orders of any product, regardless of whether the order was for toilet paper, or paper towels, or Claritin, or OxyContin. Additionally, the excessive order query was never amended or modified for specific use for identifying excessive controlled substances orders.[538] Ultimately, the DC personnel responsible for implementing this policy conceded that it was not intended to detect suspicious orders, but rather was a program designed to detect orders entered in error.[539]

A second aspect of this policy required "pickers", the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.[540] This facet of the RX Questionable Order Quantity policy was also not intended to detect suspicious orders as mandated by the security requirement, but as with the policy in general, merely allowed for the identification of orders potentially entered in error.[541]

b. *Rigid Formula Reports ("Suspicious Control Drug Order" Reports) (1998–2012):*

Walgreens submitted a monthly report to the DEA field offices containing all orders that were outside the parameters of the formula applicable during that time frame.

While Walgreens internally acknowledged, as early as 1998, the requirement to identify controlled substance orders of "unusual size[,]… unusual frequency[,]…[or] [d]eviating from a normal pattern for a store in its category",[542] Walgreens did very little to appropriately ensure that such orders were being identified, prevented, or properly reported. The "policy" containing this requirement states merely that Walgreens is generating and providing "Suspicious Control Drug Orders" reports listing orders that "may" be suspicious "to distribution centers". In 2012, Walgreens updated this "policy" to assert that "[e]ffective calendar year 2012", Walgreens SOMS system "prevents suspicious control drugs from being shipped to the stores," and thus Suspicious

[536] See D. Bish Deposition at 80:11-15.

[537] *Id.* at 101:5-13. Walgreens also claims that there were line limits in place that set a maximum upper limit on the quantity per item that could be ordered by a store, however Walgreens was unable to produce any policies, procedures, reports or other written documentation evidencing the line limits or how they were applied to opioid products. *See* E. Bratton Deposition at 191:24 to 194:16.

[538] *See* D. Peterson Deposition at 26:9 - 28:21; 260:15 -262:7.

[539] *See* J. Diebert Deposition 129:8-130:1 and D. Bish Deposition at 72:3-21;502:11-503:10.

[540] WAGMDL00749381.

[541] *See* D. Bish Deposition 110:16-114:5.

[542] WAGFLDEA00001854.

Control Drug Orders reports would no longer be generated, but again provided no detail on how such a system worked or why such measures were only newly being employed.[543]

1. ***Customer Grouping Formula (1998-2007)***

> Walgreens's "insufficient" formula for reporting suspicious orders to the DEA from at least 1998-2007 is outlined in a 2006 Letter of Admonition from the DEA to Walgreens, and was as follows:The system set its standard of deviation from a normal ordering pattern in groupings of 25 customers, based on the number of non-controlled and controlled substance prescriptions filled by each customer. The system in place determined the amount of daily prescriptions filled by each of its customers of both non-controlled and controlled substance prescriptions. This amount was utilized to place each customer in groupings each containing 25 customers. Of these 25 customer groupings, the firm calculated the average order per item of each controlled substance. The firm then took the average and multiplied that figure by three. This calculated figure was then used as the base to report suspicious orders above such figure. [544]

2. ***Formula Based on Chemical Handlers Manual Appendix E-3 (2007 – 2012)***

In May 2006 the DEA informed Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient,"[545] and "inadequate" and that Walgreens's suspicious ordering report "formula should be based on (Size, pattern, frequency)."[546] Rather than design and operate a system to identify suspicious orders, Walgreens modified its reporting of suspicious orders to the DEA to use a version of the formula described in Appendix E-3 to the Chemical Handlers Manual ("Appendix E-3").[547] Notably, the Appendix E-3 adopted by Walgreens was virtually identical to the Customer Grouping Formula that the DEA had just told Walgreens was "insufficient" and "inadequate" in that it also utilized a store average multiplied by a factor of 3 to calculate a purchase limit.[548] Despite knowing they were utilizing a formula that they had just been told by the DEA was "insufficient" and "inadequate", Walgreens began reporting to the DEA using this Appendix E-3 formula in March 2007.[549] Walgreens did not perform any due diligence on the suspicious orders identified by these reports prior to shipping

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[543] WAGFLDEA00000028.

[544] WAGMDL00709510. *See also* WAGMDL00757762 at 772-773 (multiplier of 3 was Walgreens's "determination of a suspicious order.").

[545] *Id.*

[546] WAGMDL00709508.

[547] *See* Walgreens's Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Request No. 3.

[548] WAGMDL00400357.

[549] *Id.*

the orders.[550] Walgreens claims that a retrospective analysis of the reports calculated using Appendix E-3 was performed, but the individuals that Walgreens claimed performed this analysis stated they had never seen the reports and did not perform due diligence on them.[551] This system simply reported orders that were greater than three times the store's average order for the last 13 months, and only when there were orders in excess of this formula for two or more consecutive months.[552]

Walgreens claims that in 2006 "the Detroit DEA Field Office admonished Walgreens for not basing its reporting of potentially suspicious orders on the "voluntary formula" found in Appendix E-3.[553] However, the documents Walgreens cites for this proposition do not evidence any such admonition and Walgreens has not produced any evidence that it was instructed to base its reporting of suspicious orders on the formula found in Appendix E-3 to report suspicious orders or that it was "admonished" for not doing so. [554] Nor does the record reveal any document which supports this contention. To the contrary, Walgreens produced evidence that in 2007 the DEA informed Walgreens that it did not want reports identifying all potentially suspicious transactions, but rather, only those transactions that Walgreens could not classify as not suspicious after review.[555] A memorandum written by Walgreens employee Justin Joseph outlining the actions taken during the DEA's of Walgreens's Perrysburg DC in 2006 claims that the DEA said that Walgreen's suspicious ordering report "formula" should "be based on (Size, pattern, frequency).[556] In fact, documents show that Walgreens was repeatedly told to stop sending the Appendix E-3 type of report.[557]

Further, Walgreens had guidance from the DEA that this type of "excessive report" without any due diligence performed on order did not satisfy the requirements of *21 C.F.R. § 1301.74(b).* Documents produced in this litigation evidence that three of Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas on September 11-12, 2007.[558] Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." [559]

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[550] *See* E. Bratton Deposition at 158:22 to 159:24. *See also* E. Bratton Errata.

[551] *See* E. Bratton Deposition at 160:1-23; B. Martin Deposition at 163:4 to 168:11.

[552] WAGMDL00400357.

[553] *See* Walgreens Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3.

[554] *See* Walgreens Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3.

[555] WAGMDL00387635.

[556] WAGMDL00709508.

[557] WAGMDL00660331; WAGMDL00387641.

[558] CAH_MDL_PRIORPROD_DEA07_01185382 at CAH_MDL_PRIORPROD_DEA07_01185404-5.

[559] CAH_MDL_PRIORPROD_DEA_12_00011059; HDS_MDL_00002032 at 2040.

Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."[560]

3. **Bancroft Algorithm (2008 to 2012):**

Phase I (August 2009 – September 2010)

As early as 2005 and 2006, Walgreens acknowledged that its SOM policies were inadequate and did not meet industry and legal standards, however, Walgreens did not institute a SOM program at that time.[561] In March 2008, in response to three of Cardinal Health's DCs being shut down by the DEA for suspicious drug ordering violations, Walgreens formed a five department "team" to finally "begin creating" a SOM program,[562] and, in June 2008, developed a new SOMS algorithm to begin to address the inadequacies of Walgreens's SOM policies.[563] Despite years of knowledge that its SOM was insufficient, and despite developing a sophisticated algorithm in 2008, Walgreens did not practically implement its SOM program until 2009, when it began to pilot the algorithm with respect to orders from seven (7) Walgreens stores.[564] The algorithm Walgreens developed in 2008 and began to test in August 2009 flagged the regular periodic orders for controlled substances orders that these seven Walgreens stores placed to Walgreens Distribution Centers for "tolerance" (size of the order) and "frequency" (how often the period orders were placed).

During the substantial majority of Phase I, the SOMS program was only implemented as a "pilot" or "proof of concept". [565] While the Phase I SOMS flagged some orders from these seven stores as suspicious, during Phase I Walgreens did not halt orders that violated the algorithm or take any other comprehensive steps to prevent the flagged orders from being shipped or filled.

The SOMS order flagging pilot was not implemented chainwide until September 2010.[566]

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[560] Acquired_Actavis_00441354 at 441355.

[561] WAGMDL00757193 ("internal controls that ensure compliance with DEA regulations … pertain[ing] to all company DCs … should be addressed to void potential DEA sanctions", noting that these issues had been pending and "un-remediated" since audits in 2005 and 2006, and included "suspicious controlled drug order processing and reporting" and "lack of formalized CII controlled substance policies and procedures."); *See also* WAGMDL00709508 (""suspicious ordering report is inadequate"); WAGMDL00709510 ("formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient").

[562] WAGMDL00659801 at 818; WAGMDL00709395.

[563] WAGMDL00624527.

[564] WAGMDL00667936, at 938 and 940; *see also* WAGMDL00658227.

[565] *See* E. Bratton Deposition at 207:1 to 210:7; WAGMDL00325170

[566] *See* E. Bratton Deposition at 208:10 to 209:24.

The algorithm also was only applied on an extremely limited basis, for example, reviewing only the controlled substances a store ordered from a Walgreens Distribution Center, but ignoring orders that same store was placing for those same controlled substances from an outside vendor.[567]

Rather than report the orders flagged by its SOMS algorithm, during Phase I Walgreens continued to use the formula found in the Chemical Handler's Manual Appendix E-3 to report orders as suspicious to the DEA.[568] Walgreens knew the SOMS algorithm and the E-3 formula did not flag the same orders.[569] Despite this, Walgreens did not report the orders flagged by the Bancroft Algorithm.

Phase II (September 2010 – June 2012)

In September 2010, two years after developing its SOMS algorithm, Walgreens first began to take steps to prevent certain suspicious orders from being filled. In Phase II of Walgreens's SOMS program, Walgreens flagged orders according to its SOMS algorithm on a nationwide basis, and also began to automatically reduce quantities of certain flagged orders before those orders were filled and shipped by Walgreens distribution centers.[570]

In April 2012, Walgreens created a policy describing its new SOMS program in which it asserted that the SOMS program now would "identify and modify potentially suspicious orders of controlled substances … prior to the order being sent to the warehouse for fulfillment."[571]

In addition to the fact that cutting orders without reporting the same to the DEA as suspicious fails to comply with Walgreens obligations under the Controlled Substance Act, Phase II as implemented also had significant gaps or loopholes which caused Walgreens to continue to provide its stores with suspicious quantities of controlled substances, including the following:

- Outside Vendor Orders: The SOMS program still only analyzed orders that Walgreens's stores placed to Walgreens's DCs in a vacuum and did not analyze the store orders in the context of orders which the stores were also placing, at the same time, to outside distributors like Cardinal Health, even though Walgreens has possession of and access to that information.[572] Accordingly, if a Walgreens store had already received from an outside vendor orders amounting to what Walgreens had determined to be the store's full quota for a controlled substance, the Walgreens store

[567] *See* E. Bratton Deposition at 225:21 to 226:7; WAGMDL00325170

[568] *See* E. Bratton Deposition at 155:17-22.

[569] WAGMDL00660331.

[570] WAGMDL00667936, at 940.

[571] WAGMDL00757762, at 773. *See also* WAGMDL00757759, at 761.

[572] *See* E. Bratton Deposition at 258:8-17; T. Polster Deposition at 144:18 to 145:15; WAGMDL00245768 at WAGMDL00245769.

would still be permitted to order that same full quota from the Walgreens Distribution Center. Rendering the "cutting" of orders meaningless, Walgreens knew that where it reduced a Walgreens DC order, that its store often would place the remainder of the order with an outside vendor.[573] And yet, Walgreens ignored the outside vendor orders and did not report to the DEA when stores would overtly circumvent the "cutting" of orders.

- Interstoring – In addition to obtaining controlled substances from Walgreens Distribution Centers and Outside Distributors, Walgreens stores also obtained controlled substances from other Walgreens stores through the process of "interstoring."[574] Walgreens did not consider these interstore transfers as part of its SOM analysis.[575] Controlled substance interstoring continued at Walgreens until April 2013.[576]

- Gradual Increase – the SOMS algorithm only considered 13 weeks of sales data and would recalibrate the thresholds if there was an increase in sales. Therefore, a gradual increase in sales did not result in orders getting cut.[577]

- PDQ Orders – In addition to their regular periodic order for controlled substances from the Walgreens Distribution Centers, Walgreens stores were permitted to place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days. The limits and automatic reductions Walgreens placed on stores' orders to Distribution Centers did not apply to PDQ orders, such that "a store could hit their … limit" on a weekly controlled substance order, and then place daily PDQ orders for that drug, "and far exceed" the monthly cumulative order limits put in place by Walgreens SOM program.[578] Walgreens did not remove oxycodone from PDQ ability until October 2012.[579] Other Schedule II controlled substances were not removed from PDQ until Phase V.[580] It is not clear if Walgreens ever removed schedule III controlled substance, such as hydrocodone from PDQ ability.

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[573] *See, e.g.,* WAGMDL00325129 at 130 (future "enhancements" to SOM system will "identify stores that had order quantity decreased and then placed order to vendor").

[574] WAGMDL00303305 at 306.

[575] *See* E. Bratton Deposition at 258:18 to 260:5; *See also*WAGMDL00303305 at 306 (in early 2013, Walgreens indicated that it was considering including multiple interstore requests within three weeks as a suspicious criterion, but there is no evidence Walgreens otherwise include interstore transfers in its SOMS analysis).

[576] WAGMDL00700161.

[577] WAGMDL00659801 at WAGMDL00659818.

[578] WAGMDL00705318.

[579] WAGMDL00705318.

[580] See E. Bratton Deposition at 271:20-23.

- 340B – Walgreens admits that orders pursuant to the 340B program were not included in the initial phases of the SOMS program.[581]

- No comparison to Other Stores – Only Comparison to That Store's History – Walgreens admits that, during Phase II, "each pharmacy is looked at individually."[582]

- Store and/or Product Removal – During Phases I and II Walgreens had the ability to remove both entire stores and products from the SOMS review.[583]

- Call DC for Manual Workaround: even when Walgreens began cutting orders over a certain limit, stores could simply "call the DC" to obtain a "manual work around" the purported limit. As Walgreens admitted, the DCs did not have the ability to evaluate information necessary to determine the propriety of any such overrides.[584]

Rather than report the orders flagged by its SOMS algorithm, during Phase II Walgreens continued to use the formula found in the Chemical Handler's Manual Appendix E-3 to report orders to the DEA.[585]

Orders flagged by the SOMS algorithm and reduced in Phase II were not reported to the DEA as suspicious, even though Walgreens's own documents describe these orders as "suspicious orders."[586]

Phase III and Phase IV (June 2012-November 2012)

In April 2012, the DEA served a Subpoena to one of Walgreens's three Schedule II distribution centers, the Jupiter Distribution Center, requesting, among other things, all controlled substance SOPs, communications about controlled substances, and customer due diligence files for 14 Walgreens stores, and also served a Warrant of Inspection on the Jupiter Distribution Center, authorizing seizure, among other things, all records related to distribution of controlled substances.[587] On September 13, 2012, the DEA issued an Order to Show Cause and Immediate Suspension of Registration to Walgreens on the basis that the Jupiter Distribution Center

[581] *See* N. Polster Deposition at 256:9 to 257:4.

[582] WAGMDL00757762 at 773.

[583] *See* E. Bratton Deposition at 260:6 to 261:4.

[584] WAGMDL00659801 at 817-818.

[585] *See* E. Bratton Deposition at 155:17-22.

[586] *See* Bratton Depo at p 227:1-5; WAGMDL00624503; WAGMDL00119542.

[587] WAGMDL00777158; CAH_MDL2804_01431074.

constituted "an imminent danger to the public health and safety" and ordered that Jupiter controlled substance vault be sealed.[588]

During the latter half of 2012, after the DEA instituted its regulatory investigation and action regarding Walgreens's controlled substance distribution practices, Walgreens engaged in meetings with the DEA about Walgreens's "Controlled Substance Anti-Diversion and Compliance Program" in an effort to "cooperate and avoid litigation," and represented to the DEA that it was making "new changes" to "enhance" its SOMS program.[589] Internally Walgreens claimed that it enhanced its SOMS program "in an effort to convince DEA that the proposed penalty is excessive…"[590]

While these changes narrowed some of the more significant gaps in the SOMS program, many still remained in Phase III, which ran from June 2012 through August 2012, and in Phase IV, which ran from August 2012 to November 2012.

Phase III of the SOMS program began to incorporate outside vendor orders into the overall SOMS analysis, but only when analyzing order frequency – not in analyzing the tolerance (i.e. overall limits).[591]

The other gaps which existed in Phase II also generally continued in Phases III and IV. For example, where a Walgreens store's order was reduced before being fulfilled by the Walgreens DC, Walgreens still allowed the store to order the rest of the amount from an outside vendor (i.e. Cardinal), but now tracked that information on a report.[592]

Orders flagged by the algorithm and reduced in Phase III and IV were not reported to the DEA as suspicious, even though Walgreens' own documents continue to describe these orders as "suspicious orders."[593]

Phase V (November 2012 forward)

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[588] *See* Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387654 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012) ["Jupiter Show Cause Order"].)

[589] WAGMDL00659801 at 802.

[590] WAGMDL00659270.

[591] See E. Bratton Deposition at 254:14-21; WAGMDL00325170, at 174; E. Bratton Deposition at 226:4-12.

[592] WAGMDL00492378.

[593] Bratton Depo at p 227:1-5.; WAGMDL00325170 at 172.

Phase V changed the frequency algorithm to "ceiling limits" which looked at the overall total a Walgreens store was ordering before allowing the Walgreens Distribution Center to fill the order, finally incorporating orders from outside distributors into a more comprehensive analysis.[594]

Phase V eliminated the "frequency" analysis and implemented a "ceiling threshold" in January 2013, examining all orders placed by a store within a giving time period. Walgreens also began cutting a store's order to zero when the store manually manipulated a suggested order or created an order that exceeded the tolerance or ceiling.[595]

Walgreens's own documents admit that it made the ceiling limits visible to the stores in advance via a "ceiling tool" and further admit that the purpose of this "ceiling tool" was to provide stores visibility into the likelihood of an order being flagged – and possibly a means to work around it – stating "the ceiling tool was designed to provides stores direction to place orders for controls without an order being flagged."[596]

Walgreens's last CII shipment as a distributor to Cuyahoga and/or Summit County was on March 4, 2013.[597]

3. **Reporting Requirement**.

Walgreens failed to timely report any suspicious orders for the CT1 jurisdictions. The Rigid Formula Reports, used from approximately 1985[598] through 2012, were an after-the-fact reporting which is insufficient. Walgreens has not been able to produce suspicious orders that were reported to the DEA after 2012. Using any of the methodologies described in the Expert Report of Craig McCann, it is apparent Walgreens failed to report thousands of suspicious orders arising out Cuyahoga County and Summit County.[599]

4. **Shipping Requirement.**

Period 1 (1996-2009)

Even if Walgreens had properly identified suspicious orders, which it did not, its corporate policy from 1996 to 2010 was to ship anyway. This is a blatant violation of the No-Shipping requirement. As stated earlier, Walgreens did not perform any due diligence on the suspicious orders identified by the Chemical Handler's Manual Appendix E-3 formula prior to shipping,

[594] Walgreens Second Supplemental Combined Discovery Responses, at p. 16.

[595] WAGMDL00246016.

[596] WAGMDL00095316 at 322.

[597] *See* ARCOS Transactional Data (this excludes Codeine Drug Code 9050).

[598] WAGMDL00660331.

[599] *See* Section III, "Identifying Suspicious Orders Distributed in CT1."

despite the fact that even the Chemical Handler's Manual (on which Walgreens claims it was relying) requires due diligence prior to shipment. [600]

Though Walgreens initially claimed that a retrospective review of a sample of these orders was reviewed for appropriateness[601], the Walgreens employee identified as performing this review stated that she had never reviewed these reports and did not perform due diligence on these orders.[602] Walgreens subsequently admitted no due diligence had been conducted on any of the orders identified as "suspicious" on the Suspicious Control Drug Report prior to shipment of these orders.[603] In August 2010 Dan Coughlin, Walgreens Divisional Vice President Supply Chain, sent an email to many of those involved in the development of the Bancroft algorithm asking who had been reviewing the reports generated by the Appendix E-3 formula for the past 25 years and whether any was presently reviewing "what would be considered suspicious quantities that are physically ordered and are releasing to stores?"[604] Despite the fact that this email was sent to ten people, most of whom were identified by Walgreens as having been involved in developing Walgreens's order monitoring system or in monitoring or evaluating orders, Walgreens did not produce any evidence indicating that anyone had ever reviewed these suspicious orders prior to shipment.[605]

Walgreens claims that from 2006 through the time that Walgreens stopped distributing controlled substances, Walgreens's DC personnel called stores with orders greater than a set threshold quantity and inquired whether the quantity was actually needed, before shipping the order.[606] As noted previously, this process (Rx Questionable Order Quantity) was not a due diligence practice instituted to investigate suspicious orders, but in fact was an inventory management practice intended to identify ordering errors.[607] Walgreens was unable to produce any policies reflecting what the procedures were for determining a "suspicious order" at the DC level or what the set thresholds were for any controlled substances,[608]and the Perrysburg DC personnel in charge of Schedule II and III controlled substances were never trained on suspicious orders or identifying the same.[609] In May 2012, the Perrysburg DC personnel questioned whether the quantities they typically "let go" were correct and asked for "real, updated guidance on drugs that

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[600] *See* E. Bratton Deposition at 158:22 to 159:24; *See* E. Bratton Errata. *See also* WAGMDL00395965 at 988.

[601] *Id*. E. Bratton Deposition at 160:1-23.

[602] *See* B. Martin Deposition at 163:4 to 168:11; *See* E. Bratton Errata.

[603] *See* E. Bratton Errata.

[604] WAGMDL00660331

[605] Walgreens Second Amended Obj. and Resp. to First Set of Interrogatories, Interrogatory 5.

[606] Walgreens Second Supplemental Responses to Combined Discovery, Request No. 7.

[607] *See* J. Diebert Deposition 129:8-130:1 and D. Bish Deposition at 72:3-21 and 502:11-503:10.

[608] *See* E. Bratton Deposition at 138:4-16; 142:18 to 143:2; 50:4 to 51:14.

[609] *See* J. Diebert Deposition at 61:2-23 and D. Bish Deposition at 64:19-23, 66:7-22, and 401:14-17.

are going to be an issue if the DEA audits…"[610] DC personnel further indicated that because large orders of opioids such as oxycodone, methadone, and fentanyl were so common that it was impractical to call and check large orders, and, that when the DC did call and check orders, they typically learned that the orders were "intentional" and thus appropriate to approve under Walgreens's operative DC level SOMS program.[611] This lack of written procedures and guidelines used to determine what could constitute "suspicious orders", as well as the lack of any enforcement of the policy on calling pharmacies led to a total failure of any meaningful due diligence at the DC level throughout the time period that Walgreens was distributing controlled substances.

Period 2 (2009-2012)

Walgreens admits that, since at least 2009, the DEA had instructed Walgreens to "stop what was considered suspicious drug shipments to any of our stores."[612] During the 2009 to 2012 period, Walgreens claims personnel in Rx Inventory and Loss Prevention conducted additional due diligence on potentially suspicious orders, by reviewing reports of orders hitting on the SOMS threshold limits for tolerance and frequency.[613] This additional "due diligence" consisted of a review of samples of reports of flagged orders generated by the SOMS algorithm **after the orders had already shipped,** in order to validate the algorithm's logic – not to determine whether the order was in fact suspicious.[614] Additionally, this additional "due diligence" was performed by two Walgreens individuals, one of whom dedicated a mere one to ten hours a week to review of the suspicious orders flagged by the SOMS algorithm.[615] As of August 2010, the Walgreens algorithm was generating 389+ pages of suspicious order data per week.[616]

Period 3 (2012-2014)

Pharmaceutical Integrity ("RX Integrity") was formed in 2012 as a result of the DEA investigation into Walgreens CSA violations and viewed its role as protecting the DCs and stores from losing their DEA licenses.[617] After referring to orders flagged by Bancroft algorithm as "suspicious orders" since the inception of the algorithm, in late 2012 Walgreens put together a team to "begin the determination between a suspicious order and an order of interest"[618] From this point forward, RX Integrity took the position that the orders flagged by Walgreens's algorithm were not "suspicious" under the controlled substances regulations (despite being described as such

[610] WAGMDL00751871.

[611] WAGMDL00751871.

[612] WAGMDL00660331.

[613] Walgreens Second Supplemental Responses to Combined Discovery, Request No. 7.

[614] *See* B. Martin Deposition at 169:5 to 170:4; 253:4-15.

[615] *See* B. Martin Deposition at 70:10-12; 328:5 to 329:7;

[616] WAGMDL00660331.

[617] *See* WAGMDL00101723; WAGMDL00060486.

[618] *See* WAGMDL00574824 at 825.

in Walgreens own documents), but rather were "orders of interest."[619] Furthermore, as of January 2013 the RX Integrity team only had the ability to investigate orders placed via a Controlled Substance Override ("CSO") Form.[620] The orders flagged via the Walgreens algorithm were a week old and in most cases had already shipped by the time that RX Integrity had the visibility to investigate them.[621]

RX Integrity lacked the necessary resources to perform adequate due diligence on the overwhelming number of orders identified by Walgreens's algorithm for Walgreens 5,000 plus stores.[622] In December 2012 when Walgreens's "updated" SOM program was set to "tracking" for all controlled substances chainwide, it resulted in 14,000 flagged orders that required due diligence reviews.[623] At the time these 14,000 orders were flagged, Walgreens's RX Integrity department consisted of fewer than 5 people, and at its height it only had had eleven members.[624] Walgreens had the ability to control this workload by simply increasing stores' ceiling values, thereby reducing the number of orders that would breach that ceiling.[625]

One of the mechanisms that Walgreens put in place to deal with the number of flagged orders was the CSO system, an "alternative ordering procedure" to be used in response to demand increase.[626] Orders that exceeded the Walgreens algorithm were cut to predetermined limits unless an override was approved. When Walgreens stores were close to hitting their ceiling limits they were directed to complete a CSO Form.[627] The RX Integrity team of eleven was then tasked with reviewing the CSO Forms and making decisions with regard to override approvals. At times, the RX Integrity team received between 1,000 and 3,000 CSO forms per month.[628] When CSO overrides were submitted they were routinely approved. For example, Walgreens documents show that over 95% of CSO overrides were approved by RX Integrity in both 2014 and 2015.[629]

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[619] *See* N. Polster Deposition at 174:3 to 176:18.

[620] *See* WAGMDL00414048.

[621] *See* WAGMDL00414048; WAGMDL00415348.

[622] *See* N. Polster Deposition at 133:10-13.

[623] *See* WAGMDL00659270.

[624] *See* N. Polster Deposition at 240:3-15.

[625] *See* WAGMDL00370894 at WAGMDL00414048.

[626] *See* WAGMDL00037074.

[627] *See* WAGMDL00700240; WAGMDL00095316 at 334.

[628] *See* N. Polster Deposition at 343:15-23.

[629] *See* Walgreens Presentation *State of Rx Integrity* (May 10, 2016) WAGMDL00010887 at WAGMDL00010909.

F. Henry Schein, Inc. ("Henry Schein")

Distribution Center: Indianapolis, Indiana (5315 West 74th Street, Indianapolis, IN 46268)

DEA Registrant Number: RH0162494

Transactional Data Disclosed:

Date range: 01/01/2009 through 07/27/2018[630]

Volume: Henry Schein provided transactional data for Summit County only.

Cuyahoga	Opioid Total Dosage Units (2006-2014)	Opioid Total MME (2006-2014)
	[redacted][631]	[redacted][632]

Summit	Opioid Total Dosage Units (2006-2014)	Opioid Total MME (2006-2014)
	[redacted][633]	[redacted][634]

1. Court ordered SOMS Discovery Disclosure

- *Henry Schein, Inc. and Henry Schein Medical Systems, Inc.'s Amended Objections and Responses to Plaintiffs' First Combined Discovery Requests* (11/30/2018).

In response to Interrogatory No. 2, Henry Schein disclosed a list of documents and represented that these were their SOMS policies and procedures.[635]

2. SOMS Corporate Policy Disclosed

a. 1992-1998: Early Suspicious Order Monitoring System

[630] HSI-MDL-00001612.

[631] *See* Expert Report of Craig J. McCann, Ph.D., CFA, App. 9, p. 3783.

[632] *Id*. at 3779.

[633] *Id*. at 3859.

[634] *Id*. at 3849.

[635] HSI-MDL-00000001 to HSI-MDL-00000441.

Henry Schein has had some form of a written system in place to review customer orders of controlled substances since at least March 31, 1992.[636] At that time, Henry Schein defined a suspicious order as "any order that was in excess of the thirty day or six-month thresholds as defined within the computer system."[637] Even when the system flagged an order as suspicious, various Henry Schein employees had authority to override and release a suspicious order. Although the 1992 procedures imply that the decision to ship a suspicious order should be documented – noting, "the background information developed in the decision process must be entered on the approval screen" – the procedures fail to define the background information required.[638]

Henry Schein's "Verification Procedures for Controlled Drug Orders," dated February 5, 1998, outlined the steps for maintaining a customer's DEA and prescription drug licensing information.[639] These steps included verifying that a customer's DEA and/or State Board of Pharmacy license was on file, that the licenses were valid and current, and that the quantity of controlled substances was not "in excess of the threshold levels as set forth in the suspicious order monitoring system."[640] Even though the procedures acknowledge that suspicious orders can also include orders that "deviate from a normal pattern" or "orders of unusual frequency," an exceeded order threshold is the only metric used to automatically identify a suspicious order.[641]

Orders that are "identified as suspicious . . . will pend for review."[642] However, Henry Schein only reported the orders its system initially identified as suspicious if a Henry Schein employee determined it was necessary to do so after conducting a review.[643] The procedures do not describe what such a review would require, stating merely that the head of the medical, dental or vet department would review the customer's account and determine if the orders were "compatible with the practitioner's type of practice and the customer's purchasing pattern". Henry Schein would then call the doctor to confirm that he/she had placed the order before releasing it.[644]

b. 2001-2006: Development of the Suspicious Order Monitoring system

Henry Schein made non-substantive revisions to their SOM system procedures between 2001 and 2005.[645] In September 2005, BuzzeoPDMA reviewed Henry Schein's Suspicious Order

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[636] *See* HSI-MDL-00404222.

[637] *Id*.

[638] *Id*. at HSI-MDL-00404223.

[639] *See* HSI-MDL-00404226.

[640] *Id.* at HSI-MDL-00404227.

[641] *Id.*

[642] *Id*. at HSI-MDL-00404228.

[643] *Id*. at HSI-MDL-00404227.

[644] *Id*.

[645] *See* HSI-MDL-00000082; HSI-MDL-00000073; HSI-MDL-00000139; HSI-MDL-00000056; and HSI-MDL-00000134.

Monitoring system.[646] However, despite BuzzeoPDMA's recommendations, described in detail below, Henry Schein's suspicious order monitoring policies remained essentially the same until 2007, when the company started a "Suspicious Monitoring Program enhancement project."

In the September 2005 report summarizing its review of Henry Schein's suspicious order monitoring system and procedures, BuzzeoPDMA noted multiple deficiencies, including:

- Threshold Issues: Henry Schein designed its suspicious order monitoring system to detect suspicious orders based solely upon order thresholds, and the system failed to highlight orders for frequency or deviations from patterns. Henry Schein also had no formal process in place to review threshold data on a periodic basis, nor a staff pharmacist available to review the system thresholds as stated in the standard operating procedure. Additionally, thresholds were set based on an average number of orders for each product and did not take customer categories such as size or practice into account.

- Due Diligence Issues: Henry Schein had no formal process in place to assess the appropriateness of the customer's practice in relation to the drug product ordered.

- Reporting Requirement: While Henry Schein investigated all suspicious orders, Henry Schein released all orders that it cleared from suspicious status. However, Henry Schein did not send this suspicious order activity to DEA until the end of each month, rather than "when discovered" as required by 21 CFR 1304.74(b).

In July of 2006, Henry Schein issued a revised procedures document called "Controlled Substance Monitoring & Reporting Procedures".[647] As noted above, changes to Henry Schein's suspicious order monitoring procedures during this time (and despite the recommendations for required changes provided by BuzzeoPDMA) were minimal, with the process for verification of customer orders and the review of suspicious orders remaining essentially the same.

d. 2007: Review by Cegedim Dendrite

Following a review of Henry Schein's SOM system in March and July of 2007, a Cegedim Dendrite consultant, Robert C. Williamson, sent Henry Schein a letter and report summarizing his findings on September 3, 2007.[648] Mr. Williamson specifically found that the SOM system had not changed in a substantial way from the time of BuzzeoPDMA's prior review of Henry Schein's system in 2005.[649] Mr. Williamson also noted multiple deficiencies with Henry Schein's system, including:

- Inadequate Due Diligence for New Customers: Henry Schein's new account procedures were inadequate. The Verifications Department merely confirmed that a customer had a valid DEA Registration Certificate, but they failed to capture additional information

[646] *See* HSI-MDL-00404203.

[647] *See* HSI-MDL-00000134.

[648] *See* HSI-MDL-00619797-801.

[649] *Id*. at HSI-MDL-00619798.

regarding the customer in order to determine whether the customer is a legitimate business. Henry Schein did not use a Controlled Substances Ordering Questionnaire prior to authorizing new accounts to purchase controlled substances.[650]

- Threshold Issues: Henry Schein's computer program did not identify deviations from usual ordering patterns.[651]

- Inadequate Due Diligence in Reviews of Pended Orders: Henry Schein failed to fully investigate orders that pended, the investigation did not include possible on-site interviews, and the results of the due diligence investigation were not documented.[652] Further, Henry Schein lacked standard operating procedures to memorialize the important internal controls, including individual responsibility and other management controls for releasing pending orders.[653]

- Reporting Requirement Issues: Henry Schein still did not immediately report suspicious orders to the local DEA office. Instead, Henry Schein sent a monthly report of "Suspended Orders Released" and "Pended Invoices Not Shipped".[654]

e. October 2009 to present: The "SOM" Update Project

According to a November 2, 2009 presentation by Henry Schein's Director of Regulatory Affairs, Mike DiBello, the project to update Henry Schein's suspicious order monitoring system, took place over a two-year period from September 2007 to October 2009.[655] Cegedim Dendrite consultant, Robert C. Williamson, had again met with Henry Schein officials on January 17-18, 2008, and made specific recommendations related to improving both the suspicious orders thresholds and the company's due diligence in reviewing flagged orders.[656] His recommendations included the setting up of restrictions to prevent accounts from ordering products not normally used in their practice, creating a process to monitor orders not only based on thresholds but also based on model calculations, and updating and memorializing procedures for Verification and Regulatory Affairs review processes.[657]

According to internal documents, Henry Schein did not implement this new suspicious order monitoring system until September 22, 2009.[658] In implementing this improved system,

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[650] *Id*. at HSI-MDL-00619799.

[651] *Id*. at HSI-MDL-00619800.

[652] *Id*.

[653] *Id*. at HSI-MDL-00619800-801.

[654] *Id*. at HSI-MDL-00619801.

[655] *See* HSI-MDL-00040712.

[656] *See* HSI-MDL-00386875-879.

[657] *Id*.

[658] HSI-MDL-00000119-125.

Henry Schein adopted some of the basic recommendations that BuzzeoPDMA and Cegedim Dendrite had made between 2005 and 2009 regarding thresholds and due diligence. However, Henry Schein continued to submit monthly reports of pended and suspicious orders to DEA.

i. November 2009 – New Account Setup Due Diligence Procedures

As a part of Henry Schein's new suspicious order monitoring system initiated in September 2009, Henry Schein created a new written policy so that all new accounts that ordered controlled substances would be the subject of a due diligence inquiry. During the due diligence inquiry, the new account holder would go through a preliminary phone interview and a self-assessment questionnaire.[659]

ii. 2012 – Verifications/ Due Diligence Procedures

Henry Schein's Controlled Substance Monitoring Procedure policy issued on December 3, 2012, added "Know Your Customer" due diligence procedures.[660] These additional due diligence investigation steps included additional questionnaires, a phone interview, and possible site visits. A flow chart of this written process is included on the last page.[661]

iii. 2016 and 2018 – Changes to SOM and Due Diligence SOPs

By 2016, Henry Schein's Regulatory Affairs department had completed the review, planning and agreement with Cegedim Dendrite for a SOM system threshold "Retunement".[662] Following these consultations, Henry Schein issued a new standard operating procedure for controlled substance monitoring and reporting dated March 29, 2016.[663] This version made changes to the following areas:

- Added clarity regarding pended orders and suspicious orders
- Added detail on the Know Your Customer/Due Diligence processes
- Added section covering the reporting of suspicious orders to DEA and State Authorities
- Added detail regarding inventories taken
- Added section on monthly state reporting

In 2018, Henry Schein issued additional SOM policy updates, including a policy document for Regulatory Affairs Controlled Substance Due Diligence procedures on March 2, 2018,[664] and an updated Controlled Substance Monitoring & Reporting procedures document

[659] *See* HSI-MDL-00406270-273.

[660] *See* HSI-MDL-00000194-204.

[661] *Id*. at HSI-MDL-00000204.

[662] *See* HSI-MDL-00623053.

[663] *See* HSI-MDL-00000104-112.

[664] *See* HSI-MDL-000000208-218.

issued on May 21, 2018.[665] These documents made changes to the following areas: provided an updated overview of SOMS, described and outlined procedures for federal and state suspicious order reporting, and described and outlined procedures for federal (ARCOS) and state-controlled substance transaction reporting.

3. Enforcement Actions

a. In 1998, Henry Schein received a Cease and Desist letter from the Ohio State Board of Pharmacy for the sale of dangerous drugs to persons/entities not licensed/authorized to possess them.[666]

b. On April 27, 2012, the Iowa Board of Pharmacy accepted a Citation and Warning submitted by Henry Schein in order to resolve charges that the company distributed controlled substances to an unauthorized person in violation of the Controlled Substance Act. Henry Schein was assessed a civil penalty of $5,000.[667]

c. In 2012, Henry Schein agreed to pay a $50,000 fine to settle civil allegations by the DEA stemming from distributions to a researcher at the University of Pittsburg who had been criminally charged in connection with the diversion of controlled substances.[668]

d. In November 2012, Henry Schein's Director of Regulatory Operations, Sergio Tejeda, informed the Program Director for the Prescription Monitoring Program of the Ohio State Board of Pharmacy that Henry Schein had been under reporting sales of controlled substances to the Ohio Board of Pharmacy as required for the previous two years.[669]

e. In 2014, Henry Schein Animal Health agreed to pay a $225,000 fine to settle allegations by the DEA that it sold/distributed dangerous drugs to an entity not licensed/authorized to possess them.[670]

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[665] *See* HSI-MDL-000000086-91.

[666] *See* HSI-MDL-00528774, at 777.

[667] *See* Iowa Board of Pharmacy, Case No. 2010-35OP, April 27, 2012.

[668] *See* HSI-MDL-00528774, at 777.

[669] *See* HSI-MDL-00397293-294.

[670] *See* HSI-MDL-00528774, at 777.

4. **Suspicious Orders Reported In CT1 Jurisdictions (Summit County only):**

Note that Henry Schein claimed that they were only able to produce reliable transactional data for Summit County from 2009 to the present – they did not report any suspicious orders to DEA in that time frame.[671]

2009: 0

2010: 0

2011: 0

2012: 0

2013: 0

2014: 0

2015: 0

2016: 0

2017: 0

2018: 0

5. **Due Diligence Conducted**

Henry Schein conducted limited due diligence prior to October of 2009, particularly with respect to the "Know Your Customer" process and investigations relating to potential suspicious orders. After October 2009, Henry Schein conducted varying levels of due diligence related to pended orders that will be addressed herein.

Based on my review of documents and testimony and as noted throughout this report, historically the due diligence conducted by Henry Schein has been inadequate. While Henry Schein has employed different due diligence programs over the years, a review of those programs in practice make clear that for all practical purposes, Henry Schein's due diligence efforts have fallen short of what is required. In fact, as discussed herein, Henry Schein has admitted that it lacked complete due diligence files for all of its customers until at least 2017.

6. **Opinions Related to Henry Schein:**

1. **Henry Schein failed to maintain effective controls against the diversion of prescription opiates into the illicit market in violation of 21 U.S.C.A. § 823(b)(1) [1970] in the following ways:**

[671] *See* Henry Schein, Inc. and Henry Schein Medical Systems, Inc's Amended Objections and Responses to Plaintiff's (First) Combined Discovery Requests, No. 3; Henry Schein, Inc.'s Objections and Amended Responses to Plaintiffs' First Set of Interrogatories, No. 3.

The bar graphs identified as Figures 57-65 in Schedule II to this report demonstrate a clear escalation of prescription opioids into Cuyahoga County and Summit County by dose, base weight, and MME.

A. From at least 1992 to September of 2009, Henry Schein's suspicious order monitoring system thresholds did not detect orders based upon deviations of either frequency or pattern. During this seventeen-year period, Henry Schein set their suspicious order monitoring system thresholds to detect orders based upon deviations in size *only*. In fact, as early as September of 2005, Henry Schein's own consultants, BuzzeoPDMA, had informed the company that it needed to modify the suspicious order monitoring program to include the detection of orders that deviated in both frequency and pattern, in addition to detecting orders of unusual size. Further, from 1992 until October of 2009, Henry Schein set their system thresholds to detect suspicious orders based upon the aggregate ordering history, rather than the *individual* customer's prior ordering history. The system's threshold calculations did not even consider an individual customer's purchasing patterns until Henry Schein implemented their revised Controlled Substance Monitoring & Reporting Procedures in October of 2009.[672]

B. Based upon information and belief, Henry Schein did not report any suspicious orders in Summit County from at least 2009 to July 2018.[673] Further, before the publication of the *Masters Pharmaceutical*[674] decision, Henry Schein failed to immediately report *any* suspicious orders – those of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency - to the DEA when discovered. Instead, Henry Schein referred to these controlled substance orders that their suspicious order monitoring system flagged as pended orders of interest.

Rather than immediately reporting these pended orders of interest to the DEA as suspicious orders upon discovery, Henry Schein chose to investigate them first. Pended orders that Henry Schein cleared from suspicion were released to the customer. Orders that Henry Schein did not clear from suspicion with their due diligence investigation were deemed as suspicious orders and cancelled. At the end of each month (rather than immediately upon discovery), Henry Schein submitted two reports to the appropriate field office of the DEA. The first report included those pended orders that Henry Schein had cleared from suspicious status. The second report reflected those orders that Henry Schein had deemed suspicious and cancelled after investigation.

As early as September of 2005, Henry Schein's own consultants, BuzzeoPDMA, had informed the company that it needed to start sending suspicious order reports to the DEA

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[672] *See* Rule 30(b)(6) Deposition of Shaun Abreu ("Abreu Dep.") at 237:21-239:1; 259:17-261:19; 454:12-456:24; Deposition of Mike DiBello ("DiBello Dep.") at 181:12-182:17; *also see* HSI-MDL-00404222-223; HSI-MDL-00404203-209; HSI-MDL-00619797-800; HSI-MDL-00404219; HSI-MDL-00000119-125; HSI-MDL-00404202-209; HSI-MDL-00386875-879.

[673] *See* Henry Schein, Inc. and Henry Schein Medical Systems, Inc's Amended Objections and Responses to Plaintiff's (First) Combined Discovery Requests, No. 3; Henry Schein, Inc.'s Objections and Amended Responses to Plaintiffs' First Set of Interrogatories, No. 3.

[674] *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 219 (D.C. Cir. June 30, 2017).

immediately upon discovery. Yet, it wasn't until late 2017/early 2018, following the publication of the *Masters Pharmaceutical* decision, that Henry Schein began to immediately report orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency to the DEA as suspicious orders when discovered.[675]

C. Before October of 2009, when an order pended as an order of interest in Henry Schein's system because it exceeded a threshold, Henry Schein's due diligence investigation consisted of merely sending a one-page questionnaire/letter to the customer and reviewing their responses before determining if the order could be shipped.[676] After October of 2009, Henry Schein implemented "Know Your Customer" components, including on-site visits and potential telephone interviews with the customer to determine if a pended order of interest (an order that deviated in size, frequency, or pattern) could be shipped.[677] Henry Schein did not have any specific standard operating procedure in place for keeping a written record of due diligence investigations of pended orders of interest until October of 2009.[678]

D. Before 2012, Henry Schein did not have a written policy relating to its "Know Your Customer" due diligence obligations.[679] Further, Henry Schein's Regulatory Affairs department noted in November of 2013 that the company did not have "Know Your Customer" due diligence information for sixty percent of their customers and had only varying degrees of completed due diligence for the remaining forty percent.[680] Henry Schein's head of Regulatory Affairs, Sergio Tejeda, even noted in an August 6, 2013, email that Henry Schein's lack of Know Your Customer due diligence was the "area of most risk."[681] Tejeda further noted that Henry Schein still needed to conduct due diligence inquiries for 27,000 customer accounts, which would take Henry Schein "3-4 years to become current/fully compliant with DEA due diligence."[682]

In fact, Henry Schein did not obtain complete due diligence files for all of its customers until sometime in 2017, a process that required the company to hire at least twelve or more additional staff members in the company's verifications and regulatory departments between 2013

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[675] *See* Deposition of Jeff Peacock ("Peacock Dep.") at 153:1-24; DiBello Dep. at 157:9-24; 267:9-270:12; Abreu Dep. at 55:12-57:23; 64:11-67:13; 71:4-73:21; 83:10-21; 146:15-148:16; Deposition of Sergio Tejeda ("Tejeda Dep.") at 318:5-320:7; 330:24-331:12; *also see* HSI-MDL-00404202-209; HSI-MDL-00021781-82; HSI-MDL-00606634-36; HSI-MDL-00647221-23; HSI-MDL-00486513-14; HSI-MDL-00569496.

[676] *See* Abreu Dep. at 51:18-53:18; 74:3-75:24.

[677] *Id*. at 127:18-129:22.

[678] *See* Abreu Dep. at 75:3-24.

[679] *See* HSI-MDL-00000194-204.

[680] *See* Abreu Dep. at 294:21-295:7; 308:10-310233:13-134:17; 135:10-22; 144:24-145:9; 149:15-150:21; Tejeda Dep. at 232:11-15; 233:14-17.

[681] *See* HSI-MDL-00552881.

[682] *Id*.; *also see* Steffanie-Oak Dep. at 74:9-78:1; 98:15-20; Tejeda Dep. at 222:6-16; 225:11-227:9; 233:18-234:15; 248:23-249:3.

and 2017.[683] Further, as of 2018, Henry Schein may still approve a pended order of interest without contacting the customer, relying only on a due diligence letter from a prior pended order of interest with that same customer.[684] Currently, Henry Schein does not perform any criminal background checks or medical/dental board disciplinary checks on any of their doctor customers as part of their due diligence inquiry.[685]

V. MANUFACTURERS

It is my expert opinion that manufacturers of opioids, as DEA registrants, have the same duties as wholesalers to maintain effective controls to prevent diversion of controlled substances into other than legitimate medical, scientific, and industrial channels.[686] The fact that manufacturers hold a different position in the supply chain, and have different sources of information and knowledge, does not change the underlying duty.

Specifically, manufacturers of opioids must, among other regulatory requirements, maintain effective controls to prevent diversion, which include, but are not limited to, the following elements:

1. Design and operate suspicious order monitoring systems that operate effectively to identify, report, and not ship suspicious orders.[687]

2. Make use of all relevant prescribing and transactional data and information they obtain in the course of their business activity to identify and prevent diversion and identify suspicious orders.

Manufacturers must ensure that their direct customers—for the most part, distributors—have sufficient controls in place to prevent diversion of controlled substances. Manufacturers, initially and then periodically, must verify that their customers maintain effective controls to prevent diversion.

Manufacturers must review the orders that distributors place with them to detect suspicious orders, which include, but are not limited to, orders of an unusual size or frequency or that deviate from the normal pattern.[688] Upon discovery, manufacturers must report and not ship these orders.

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683 *See* Abreu Dep. at 310:15-314:15; *also see* Peacock Dep. at 69:22-71:9; 129:11-130:24.

684 *See* Abreu Dep. at 255:6-256:13; HSI-MDL-00404203-209.

685 *See* Peacock Dep. at 132:22-133:1; *also see* Steffanie-Oak Dep. at 105:1-106:23.

686 21 USC § 823 (b)(1); 21 CFR § 1301.74(b).

687 21 CFR 1301.74(b).

688 *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 221 (D.C. Cir. 2017) ("Section 1301.74(b) defines suspicious orders as "includ[ing]" orders of an unusual size, pattern, or frequency, and it is well established that the word "include" often precedes a list of "illustrative" examples, rather than an exclusive list of

These orders may not be shipped unless the manufacturer conducts and documents its own due diligence investigation of these orders and dispels the basis for its suspicion. That does not mean simply relying on the representation by a distributor that there is a reasonable basis for the order. Actual (and documented) investigations to verify the information must be conducted by the manufacturer to confirm that the order is not diverted into other than legitimate medical, scientific, and industrial channels.

I am aware that some manufacturers have some data on doctors' prescribing of opioids, which manufacturers purchase from companies like IQVIA (formerly IMS). It is my understanding that manufacturers obtain this data in order to target and monitor their marketing efforts. This data also allows manufacturers to identify prescribers who prescribe opioids in volumes, types, doses, and combinations, or with frequencies that are indicative of diversion.

I am also aware that manufacturers also have access to chargeback or fee for services data (collectively, "chargeback data"), which is provided by distributors. This data provides transaction information allowing manufacturers to determine who purchased its drugs, in what volumes, and in which doses. Using chargeback data, manufacturers could identify pharmacies or other customers whose orders of opioids were of an unusual size, frequency, or pattern, or suspicious in other ways that are indicative of diversion. Manufacturers could also determine whether a pharmacy is obtaining opioids through multiple distributors, a red flag of diversion. Manufacturers could also use chargeback data to monitor the geographic distribution of their drugs in order to assess whether their drugs are being supplied to hotspots of opioid abuse or in volumes that are disproportionate to a legitimate market in an area. Based on the documents I reviewed, including documents from Purdue Pharma, it is clear that manufacturers could and did identify the largest prescribers and dispensers of their drugs.

Using relevant data acquired by a manufacturer for compliance purposes is part of maintaining effective controls to prevent diversion. This obligation was acknowledged by Mallinckrodt in the Memorandum of Agreement Mallinckrodt entered with the United States in 2017.[689] Mallinckrodt confirmed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b)" and "utilize all available transaction information to identify suspicious orders of any Mallinckrodt product."[690] Mallinckrodt agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[691] Mallinckrodt also acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their

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indicia of an identified wrong. [internal citations omitted]. […] Reading section 1301.74(b)'s listed characteristics as exemplary rather than exhaustive, DEA reasonably concluded that other indicia may also raise suspicions about an order for controlled substances.")

689 Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), *available at* https://www.justice.gov/usao-edmi/press-release/file/986026/download.

690 *Id.* at 4

691 *Id.*

direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the resolution, Mallinckrodt agreed that it could and would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[692]

Thus, to comply with the law, manufacturers that have prescribing and chargeback data are obligated to incorporate that data into their compliance programs to meet their duties to maintain effective controls to prevent diversion. Put another way, manufacturers "know what they know" and must put that knowledge to use when they know it to prevent diversion. Manufacturers must analyze this data using metrics or methods that are reasonably designed to identify suspicious orders and that are not so high that they fail to detect suspicious orders. As DEA had pointed out: "[r]egistrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."[693] Changing these metrics or methods in a suspicious order system to avoid flagging too many suspicious orders is not an effective control on diversion. These metrics must look specifically at drugs (or National Drug Codes, known as "NDCs") that are known targets of diversion, and not just at drug families. In addition, manufacturers must conduct and document a due diligence investigation to ensure that the drugs are not being diverted.

Manufacturers' sales representatives provide additional visibility into the manufacturers' downstream customers purchasing their products. These sales representatives have on-site interaction with doctors' offices and pharmacies through regular visits. These visits allow the manufacturers the ability to observe red flags of diversion – long lines, potentially inappropriate customers, cash payments, and other signs of abuse that would have alerted them to potential diversion of opioids. These observations of red flags also must be integrated into manufacturers' compliance programs.

An example of sales representatives ignoring signs of diversion is illustrated in the case of Dr. Adolph Harper, Jr., a physician in Akron, Ohio. Although his specialty was obstetrics and gynecology, Harper prescribed a substantial volume of opioids.

On October 20, 2014, Harper pleaded guilty to one count of conspiracy to traffic drugs, four counts of health care fraud and sixteen counts of drug trafficking. He was subsequently sentenced to ten years imprisonment. The Department of Justice's news release regarding Harper's sentencing indicated that Harper distributed "hundreds of thousands of doses of prescription medications – including OxyContin, Percocet, Roxicet, Opana and others – from his

692 2017 Mallinckrodt MOA at 5.

693 *See* MNK-T1_7146630, Ratliff Ex. 8 (letter from Deputy Assistant Administrator Joseph Rannazzisi to Mallinckrodt (Dec. 27, 2007)).

medical offices in Akron between 2009 and 2012."[694] The sentencing memorandum indicates that at least eight of Adolph Harper's patients died as a result of drug overdoses.[695]

In the sentencing memorandum, prosecutors described an office environment that should have alerted any sales representative who visited Harper's office: "The atmosphere of Harper's office, like his prescribing practices, was also more akin to street-level drug trafficking operation rather than a medical office. Harper's customers often waited for hours to see Harper, and many of these customers exhibited behavior consistent with drug abuse. Witnesses reported seeing customers passed out in the hallway and office while waiting to see Harper, or vomiting or urinating on the floor in the waiting room. Customers were also combative and aggressive with Harper's staff members if there was any delay in receiving their drugs."[696]

I reviewed a declaration from Ramona Harrison, who was a receptionist at Harper's office from 2010 through January 2012.[697] Harrison said that most of Harper's patients appeared to be drug addicts. They often looked disheveled and acted like they were "high" on drugs. Harper's waiting room was usually full, with some people needing to stand because there were not enough seats. Many patients "nodded off" while they were waiting to see the doctors. Others were belligerent to the staff or argued with other patients in the waiting room. Harrison noted that some patients even urinated on themselves and some patients periodically vomited in the water fountain.[698]

I am informed that, from 1994 through 2005, Harper was called upon at least 109 times by Purdue sales representatives.[699] Purdue's last recorded call to Harper's office occurred on September 14, 2005.[700] Two months later, on November 17, 2005, a Purdue email stated, "Purdue determined that the sales representative should cease sales calls on Dr. Harper."[701] I have not seen any documentation that Purdue reported Harper to state or federal authorities.

Based on documents I reviewed, Endo, Cephalon, and Janssen also visited Harper and held programs that he attended, and he was marketed Opana, Actiq, Nucynta, and Kadian.[702] Harper was eventually removed from Endo's call plan according to an April 20, 2012 document, with the

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694 "Akron Doctor Sentenced to 10 Years in Prison For Illegally Prescribing Painkillers, Even After Patients Died," U.S. Dep't of Justice Press Release (Feb. 13, 2015) https://www.justice.gov/usao-ndoh/pr/akron-doctor-sentenced-10-years-prison-illegally-prescribing-painkillers-even-after.

695 PLTF_2804-000013676 at 5.

696 *Id* at 4.

697 PLTF_2804_000004562.

698 *Id*.

699 PPLPMDL0030005334.

700 *Id.*

701 PPLPMDL0030005327.

702 ENDO-OPIOID_MDL-00673563; TEVA_MDL_A_02416207; JAN-OH-00006800.

explanation: "License is being investigated and has made local news due to questionable actions."[703] This indicated that the removal was based on media reports, as opposed to feedback from Endo representatives in the field. I am also informed that, according to DEA ARCOS data, between 2006 and 2009, Harper directly purchased opioids directly from Henry Schein.[704]

According to prosecutors' sentencing memorandum, several Akron-area pharmacies began refusing to fill Adolph Harper's prescriptions.[705] Rite Aid store 3182 in Akron continued to fill Harper's prescriptions and requested an increase in its oxycodone thresholds from McKesson after the store received an influx of Harper's patients turned away by another Rite Aid branch.[706] Emails obtained from McKesson disclosed that in September and October 2011, Rite Aid store 3182 requested that McKesson increase its threshold on oxycodone by 15 percent because of "increased activity from a local pain mgmt. doctor," Adolph Harper.[707] It appears McKesson approved the first request, but denied the October 2011 the additional increase. Oriente wrote that Harper "may be an issue that you may want to do additional due diligence on. He is an Ob/Gyn not a Pain Management Specialist."[708] Oriente included complaints about Harper from individuals who had posted to the website Vitals.com:

- September 29, 2011: "No one is filling his prescriptions! … some of us are very sick and not just drug addicts!"[709]
- July 15, 2011: "YOUNG PEOPLE ARE DYING BECAUSE THIS MAN WILL GIVE PAIN PILLS AND XANAX TO ANYONE! PLEASE SOMEONE STEP IN BEFORE ANOTHER LIFE IS LOST."[710]
- July 6, 2011: "gives my daughter any pills she wants as long as he can be a pervert once a month and check her, in trouble with drug board, he will get you addicted to any pills, he is not a doctor he is a drug dealer with his own daughters as accessories."[711]

A Director of Loss Prevention for Rite Aid responded, "I agree, we ran a report and checked his DEA number and saw the same thing. We have the [Pharmacy District Manager] reviewing a checklist to visit the clinic. No increases at this time."[712]

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703 ENDO-OPIOID_MDL-02816744 & END00746489

704 HIS-MDL-00001612; HIS-MDL-00648726.

705 PLTF_2804_000013676 at 4.

706 MCKMDL00632908; MCKMDL00626683; PLTF_2804_000013676 at 4.

707 MCKMDL00632908 & MCKMDL00626683

708 MCKMDL00627631.

709 *Id.*

710 *Id.*

711 *Id.*

712 MCKMDL00634992.

It is my expert opinion that:

1. Sales representatives who visited Dr. Harper should have been aware of and reported the signs of diversion at his practice.

2. A distributor who directly supplied opioids to Dr. Harper should have visited his practice and observed and reported signs of diversion.

3. The increase in volume associated with Dr. Harper's prescribing should have—and did—alert distributors and pharmacies to Dr. Harper's suspicious prescribing, and those entities should have reported Dr. Harper.

Manufacturers that knew or should have known of suspected diversion of their products by prescribers and/or pharmacies through relevant transaction data, sales representatives' visits, or any other means are required to take action to maintain effective controls to prevent diversion. Manufacturers should have investigated whether the suspected diversion was the result of deficiencies in their distributors' overall compliance program, including the suspicious order monitoring system that supplied their products to the prescribers and/or pharmacies. The obligation for taking action exists when the diversion was or should have been discovered, even if that was after the orders were shipped to those customers, to prevent diversion and protect the public interest. To the extent that a manufacturer was aware of potential diversion, whether by a distributor, prescriber, or pharmacy, the manufacturer should have reported the relevant conduct to the DEA. In addition, manufacturers that continued to distribute their products with reason to believe those products were being diverted demonstrated a failure to maintain effective controls against the prevention of diversion.

In sum, whatever specific methodology a manufacturer used (or failed to use) to implement effective controls to prevent diversion, to design and operate a system to disclose suspicious orders, all manufacturers had the obligation to: (1) evaluate all relevant data and information available to them to prevent and report diversion; (2) identify, report, and stop shipment of suspicious orders of opioids; and (3) if shipping those suspicious orders, conduct sufficient due diligence to ensure that those orders are not being diverted into other than legitimate medical, scientific, and industrial channels. Manufacturers that do not have effective systems to carry out these obligations, or do not consistently or sufficiently implement these systems, failed to comply with the law.

Based (a) on my education, training and experience, (b) the law, regulation and practices in the area of CSA enforcement, and (c) on my review of document and testimony provided in this case (MDL 2804), I am of the opinion to a reasonable degree of professional certainty:

1. Manufacturers with relevant transaction data including the distribution, dispensing, and prescribing of their opioids by their direct and downstream customers had an obligation to utilize that data in their compliance programs. The failure to integrate that data into their

compliance programs was a failure to implement and/or maintain effective controls to prevent diversion.

2. Suspicious order monitoring programs that use rigid multipliers of two or three times the average purchase amount to trigger or disclose a suspicious order do not effectively identify suspicious orders.

3. Suspicious order monitoring programs that are designed to only evaluate orders by drug code or by drug family and fail to assess specific NDCs that are known targets of diversion mask potential diversion and are ineffective.

4. Manufactures that identify suspicious orders and ship those order must conduct and document a due diligence investigation to ensure those drugs are not being diverted into other than medical, scientific and industrial channels or they are failing to maintain effective controls to prevent diversion.

5. Manufacturers that adjust their programs for identifying suspicious orders in order to reduce the number of orders that were identified as suspicious, without regard to whether those orders were suspicious or not, fail to maintain effective controls to prevent diversion.

Set out below, based on my review of documents produced and testimony given by defendants in this litigation, are examples of systemic failures of compliance in the various manufacturers' obligation to maintain effective controls and suspicious order monitoring programs.

A. ALLERGAN

Based on the evidence I have reviewed in this case, Allergan and its predecessor entities failed to maintain effective controls to prevent diversion, failed to design and operate adequate suspicious order monitoring systems, and failed to take reasonable steps to prevent the Allergan entities' products from being diverted. This conclusion is based on my review of the evidence including the following facts:

1. In 2012, Watson Pharmaceuticals, Inc. purchased Actavis, Inc., and the combined company took the "Actavis" name.[713] In March 2015, Actavis purchased Allergan, Inc. and, renamed itself again to "Allergan."[714]

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[713] https://www.Allergan.com/news/news/thomson-reuters/watson-pharmaceuticals-inc-is-now-actavis-inc The Allergan Defendants include Allergan plc, Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, as well as other related subsidiaries.

[714] https://www.Allergan.com/news/news/thomson-reuters/actavis-plc-is-now-Allergan-plc. Through a 2013 acquisition, the company had become a "plc" and moved its headquarters to Ireland to take advantage of "a favorable tax structure" but kept its executive headquarters in New Jersey, USA. *See* https://www.Allergan.com/news/news/thomson-reuters/actavis-to-acquire-warner-chilcott-to-create-premi

2. Before the 2012 merger, Actavis produced twelve different generic opioids including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and generic Duragesic (a fentanyl transdermal patch).[715] Pre-merger Actavis had the same rudimentary threshold-based SOM system in place from November 2000 through October 2012.[716] Under that system, the Customer Service group printed a report "several times a day" showing any controlled substance order that was "25% over the customer's rolling average" of orders placed over the prior six months.[717] Then, according to an internal document, "Customer Service reviews (eyeballs) the suspicious order report throughout the day (when a new report is created)" and "any order that looks unusual is investigated and any unusual items are cleared before the order is released."[718]

3. In February 2009, Senior Manager of Actavis's Customer Service Department, Nancy Baran explained to her boss why the existing pre-merger Actavis process was inadequate to "prevent shipping excess product":

> For starters, the report is not cumulative. For example, if a customer's monthly usage is 3000 units - they can order 2999 units every day of the month and it would not be caught. At the same time, the % of times an order comes up on this report where we would actually stop the order is a fraction of 1%. Orders come in all day long over the 25% threshold. [719]

Baran further stated

> If we stopped to question and put on hold every one of these orders, it would be crippling. The intent of the DEA suspicious report was designed to prevent excessive shipments of controlled products. In my opinion, it does a lousy job at even that."[720]

4. Actavis employee Noemi Rebeco, who oversaw the day-to-day implementation of the system wrote in August 2009 that "DEA Analyst Omar Plaza" would check the report "daily" and then "select customers that are exceeding the normal orders (over 25-50%) …

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715 *See* Allergan Kaufhold Ex. 3-4 (listing the Amended New Drug Application ("ANDA") number for each of the pre-merger Actavis generic opioids.

716 Woods Depo. Ex. 12 (Allergan_MDL_02081243); Ex. 13 (Allergan_MDL_02128514). Mary Woods served as the Corporate Representative of the Allergan Defendants with regard to Suspicious Order Monitoring issues. The first 24 exhibits to her deposition are the SOM SOPs the Allergan Defendants said were in place.

717 Woods Depo. Ex. 12. at 2.

718 *Id*.

719 Allergan_MDL_02128035

720 *Id*.

[choose] the ones that should be investigated … get the reply from customer service advising the reason of the large Order (most of the time trade show promotions) and send to the local [DEA] office once a month a copy of the 'suspicious report.'"[721] Baran remembered only one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA as such, but testified she did not "know any details about it."[722] All other pended orders were cleared and released.[723]

5. As the above-cited evidence shows, the 2000-2012 Actavis system only flagged orders unusual in size; it did not flag orders unusual in frequency or unusual in pattern in real time. In my opinion, the rigid formula used did not satisfy regulations requiring registrants to detect and investigate suspicious orders. The system did not utilize any downstream customer information available to Actavis, did not differentiate among NDC codes for drugs with a higher risk of diversion, and did not automatically stop orders from shipping. Although Actavis mailed reports to the DEA of orders that were identified in the system from 2009-2012, the lack of any analysis of such data made the reports meaningless. It was not an effective control and Actavis employees recognized as much. Yet the system remained in place until 2012.[724]

6. In September 2012, Actavis was implementing a statistics-based more modern SOM system designed by the Buzzeo/Cegedim group to detect "orders of interest" in "Direct Customer sales."[725] On October 1, 2012, it began working alongside Actavis's prior system.[726] Until that date, the company had used the SOM system as described in November 2000.[727]

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721 Allergan_MDL_04333369. The monthly reports Plaza mailed to the DEA between July 6, 2009 and July 14, 2012, make clear that the orders listed were from the automated system. See Allergan_MDL_03328387 (noting that ("[t]his letter is to report suspicious purchase orders during the month of June 2012"). I have seen no such reports outside of the July 2009 through July 2012 timeframe.

722 Baran Deposition, 303:7-304:10.

723 *Id.*

724 A separate program from January 2011 designed by Actavis's marketing group, tracked only "oxycodone IR suspicious orders." Woods Depo Ex. 14 (Allergan_MDL_00490306). The marketing program compared monthly order rates and noted "any individual customer locations that have ordered 50% or greater than their established six month order average." *Id.* It was not designed to track any DEA regulations, and after three months of trials, it was apparently abandoned. Acquired_Actavis_00665233 (March 24, 2011 email discussing SOP).

725 Woods Depo. Exhibit 15 (Allergan_MDL_01684748).

726 Allergan_MDL_03380778 (Thursday October 4, 2012 email noting that "we went live on Monday with our enhanced Suspicious Order Monitoring" system).

727 A separate system, titled "Indirect Customer Sales" also was issued in late 2012. Woods Depo. Exhibit 16 (Allergan_MDL_01979834). This SOP, which was to focus on customers of Actavis's direct customers using chargeback and other data, was never implemented. As the contemporaneous notes of a Watson employee noted, Actavis assigned "no resources," or personnel, to carry out the indirect SOP. Woods Depo. Ex. 36 at 12("Also prepared to work on the indirect side, no resources but have SOP's – work has been completed already").

7. At the same time Actavis was preparing to implement the Buzzeo/Cegedim SOM system, its personnel were called to meet with the DEA. On September 12, 2012, five Actavis employees met with the seven DEA personnel at its Arlington, Virginia office for about three hours to discuss opioid diversion. A DEA record produced in the litigation memorializing the meeting states that, among other things, Barbara J. Boockholdt, Chief, Regulatory Section, told the Actavis employees that:

   a. "[A]ddicts are coming from around the country to Florida and are specifically seeking oxycodone 15mg and 30mg tablets."
   b. "[I]n Florida eleven people per day are dying from oxycodone overdoses and seven babies are born each day addicted to opiates."
   c. [redacted] Some of the pharmacies had purchased well in excess of a million dosage units per year. This is an obvious concern to DEA and must be addressed by Actavis."
   d. "Florida's prescription drug laws have traditionally been very lax and because of that and the influx of pain management clinics oxycodone sales went out of control."
   e. "[B]ecause of the amount of oxycodone prescriptions being written, Florida, specifically South Florida has more pending pharmacy applications than all other states combined. Statistics are now showing this problem is spreading north into Georgia, Tennessee, Kentucky, Ohio and West Virginia."[728]

8. The memorandum also states that Leonard Levin, Staff Coordinator, Regulatory Section described various activities that are required to maintain effective controls to prevent diversion and told Actavis's Baran that:

   a. "Actavis should send someone from their compliance team to visit pharmacies who were receiving their products in south Florida, in order for them to witness the long lines at pain clinics, out of state license plates, questionable clients, security guard(s) in the parking lots, and signs stating cash payment only."
   b. Actavis employees should "get to know their customers, visit distribution sites, visit customers of those distributors, check on customers' suspicious order monitoring systems, review due diligence files, and obtain printouts of pharmacies or practitioners who are receiving Actavis products."
   c. "[I]f their customers refused to provide them with sales information Actavis should consider cutting them off."
   d. "Actavis [should take a] serious look at their quota request, review their suspicious order monitoring system, visit their customers to review their

728 US-DEA-00000001

suspicious order monitoring systems as well as their due diligence files, ask to see their customers' top customers for Actavis products, and contact their local DEA Office with any questions or issues."[729]

9. The DEA presentation included slides "compiled from ARCOS reports [Actavis had] previously submitted to DEA" showing the massive amount of Actavis opioids being shipped to Florida compared to other states.[730] [redacted]

10. Actavis employees remain defensive regarding the meeting. Ethics & Compliance Officer Michael R. Clarke testified that the meeting was "ostensibly for the DEA to talk to us about our anti-diversion efforts," but that "the tone and the tenor of the meeting . . . made it less productive than it could have been" because, instead of treating the Actavis individuals "as professionals," the DEA looked at and talked to the Actavis representatives "as street

729 *Id*

730 US_DEA_00000092

731 US_DEA_00000100

dealers."[732] "[T]hey described it," Clarke continued, "without using these specific words, but in a way that we would just manufacture, put the product out on the street, and not have a care as to where it went" and "described finding or seeing or obtaining product, you know, opioid products that seemed to be diverted relatively easily."[733] In late October 2012, Actavis had a follow-up meeting with two field representatives from the DEA's Newark, New Jersey office where, according to Clarke, DEA requested a reduction of approximately 30%-40% in Actavis' manufacturing quota for oxycodone.[734] Actavis' then CEO, Doug Boothe, however, rejected the DEA's request. .

11. The deficiencies in pre-merger Actavis' failures to prevent diversion, design and operate adequate suspicious order monitoring systems, and take reasonable steps to prevent diversion were summed up by Boothe's testimony. Boothe – again, the CEO of pre-merger Actavis – testified that Actavis' responsibility was only to making certain orders were received from licensed pharmacies and were within numerical suspicious order monitoring thresholds, and that Actavis had no responsibility (or accountability) for preventing diversion:

> Again, I don't think we had responsibility for, accountability for preventing diversion. We had responsibility and accountability for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds as it was described earlier then with the Buzzeo model or the more statistical model. So we -- that was our responsibility. Once it goes outside of our chain of custody, we have no capability or responsibility or accountability to -- or at least my understanding, I'm not a lawyer, as it relates to diversion. So, once we ship a valid order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.[735]

It is my opinion that this statement reflects an inaccurate interpretation of Actavis' statutory and regulatory requirements.

12. The core of the Watson SOM system, like the early pre-merger Actavis system, dated to the early 2000s.[736] A 2001 memo says Watson's inventory system automatically compiled a "12-month average" of customers' various orders, and reported violations of it Customer Service personnel (also known as the "Call Center" group).[737] A May 2004 Operational Procedure added a "SOMS multiplier table" to the system that increased the level at which

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732 Clarke Depo., 86-89.

733 *Id*. at 90-91

734 *Id*. at 98-102.

735 Boothe Depo., 408-09.

736 Woods Depo. Ex. 1 (Allergan_MDL_01844864).

737 *Id*..

the inventory system would alert a potentially suspicious order.[738] The multiplier, set by people instead of an algorithm, placed a different value for various "classes of trade," and orders from wholesalers, distributors and chain pharmacies were regularly allowed at triple the historical average, or more.[739]

13. The Watson system affirmatively allowed customers to get around violations by canceling the order, or cutting the quantity.[740] Mary Woods, who was in charge of the Watson SOM system, stated that Watson "never needed to file a report" because they would cut or cancel the order instead.[741] This policy was consistent through 2012.[742] In 2012, Watson merely required that "[i]f the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation."[743] Before the merger with Watson, Actavis policy did not allow reducing or cancelling an order.[744] After the merger, the combined company adopted the Watson SOM system, and cutting or cancelling was not generally prohibited. Watson also allowed orders to be shipped based on "an employee inside of the company [including salespeople] providing the justification" in "an email."[745] Watson Call Center/Customer Relations Operation did not add any new staff to handle the SOMs "validations" between 2009 and 2012, but the number of validations increased substantially.[746] In 2009, each "administrator" handled an average 62 "SOMs validations" per month.[747] In 2010, that number jumped to an average of 180, and in 2011 the number

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738 Woods Depo. Ex. 3 (Allergan_MDL_01839001).

739 Allergan_MDL_02181128 at '1150 (noting that the "SOMS Multi" for wholesalers was "3"); see also *Id*. at '1131 (noting that the "SOMS Multi" for "chain" stores was "6"). The wholesaler/distributor and chain store multipliers apparently covered "99 percent of the orders" in the system. Allergan_MDL_02578082

740 Allergan_MDL_01839001

741 Woods 1/10/19 Depo Tr. at 25:18-31:16, Woods Depo. Ex. 30 ("[a]ny time there was a question during the order process of a suspicious order quantity, we went (and still follow the same procedure) back to a customer to let them know we would need to notify the DEA due to the quantity they wanted to order. In response, they either reduced the quantity or cancelled the order").

742 Allergan_MDL_02146521 at 2 (July 2011 SOM policy); *see also* Allergan_MDL_03952774 at 9 (April 2007 SOM policy); Allergan_MDL_1839002 at 2 (May 2004 SOM policy).

743 Allergan_MDL_01175581.

744 Allergan_MDL_03368470 (Baran PowerPoint presentation making clear that "'Cutting' orders to a volume that puts the order under a threshold is not acceptable," and that the "DEA has stated on this topic, 'That is like saying a little bit of diversion is okay'").

745 Woods Depo. I, 140:3-141:9.

746 Woods Ex. 35 at Allergan_MDL_03802654

747 *Id*. at 2660.

reached 280, a 350% increase over 2009.[748] Woods, who oversaw the system, did not seek to add more personnel at any time.[749]

14. Like Nancy Baran at Actavis, Thomas Napoli, Watson's (and then post-merger Actavis's) DEA Compliance Chief, made clear that the system did not comply with the DEA laws and regulations. In November 2008 Napoli wrote a memo stating that "[i]t is highly recommended that industry utilize a 'total SOM model.' This model favors a more statistically-based model that dynamically evaluates a variety of order characteristics to determine whether an order should be pending. Characteristics include order size, ordering frequency, ordering patterns and percentage of CS ordered." [750] He continued that "[t]his approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold."[751]

15. Starting in 2011, Napoli advocated to hire Buzzeo/Cegedim to create a new system, just as Baran had at Actavis. Napoli wrote that, among other things, the requirement of "manual effort is very labor intensive, as the current system is not configured with any analytical tools to support timely and accurate decision making. This approach also introduces the element of 'human interaction' in the order evaluation process."[752] A 2012 PowerPoint from Napoli's files notes that Cegedim had "produced a written report" and under "Findings" noted that the multiplier threshold was "not consistent with specific requirements noted within regulations and guidance," that Watson's system "evaluates at SKU level," left open the "possibility of distributing orders across multiple SKU's without detection," and that Watson's system did not "evaluate listed chemicals."[753] The PowerPoint made "Recommendations" including developing an SOM system to "Fully address specific regulatory requirements," and that system was "Budgeted for 2012 Implementation."[754] But the new system was never implemented, and when Watson bought Actavis, the combined Company reverted to the Watson system until 2015 when it announced it was selling all of its generic drugs and various corporate subsidiaries to Teva, and as Napoli said, Teva "already had their own program in place for Suspicious Order Monitoring."[755]

Without restating every finding laid out above, I conclude that from 2000 until 2016, Watson, post-merger Actavis and Allergan used an SOM system with a threshold based automated

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748 *Id*.

749 See e.g. Woods Ex. 33, Allergan_MDL_02187056 at 7060 (noting static headcount in "SOMS Admin" and "Order Administration-Support").

750 Napoli Depo. Ex. 1 (Allergan_MDL_0353513)

751 *Id*.

752 Allergan_MDL_02467546.

753 Allergan_MDL_02468983 at 8987-8989.

754 *Id*. at 8990-91.

755 *Id*. at 324: 3-12; After the sale, Napoli said, he "was laid off." *Id*. at 325:19.

inventory component. Like the pre-merger Actavis system, it only looked for orders of unusual size and not for frequency and/or pattern in real time. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system did not utilize any downstream customer information available, did not differentiate among NDC codes for drugs with a higher risk of diversion, and only manually stopped orders from shipping. The companies' failure to identify suspicious orders was known among their employees. It was these same employees that cut or reduced orders in order to avoid filling a suspicious order. The SOM was not an effective control and the Watson and Actavis employees recognized as much. Yet the system remained in place until 2016, and was not replaced. Now, Allergan asserts that as a "virtual manufacturer" that outsources its manufacturing, transport and delivery systems, it is no longer a DEA registrant with regard to Kadian and Norco, and need not have a suspicious order monitoring system at all.[756] In my expert opinion, there is no category of "virtual" manufacturers, and Allergan cannot delegate its duties to prevent diversion.

B. JANSSEN

Based on the evidence I have reviewed in this case, Janssen failed to maintain effective controls to prevent diversion by failing to implement adequate compliance to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. Janssen's SOM program began in 2006 with its first Standard Operating Procedure for its SOM policy, in which Janssen wrote that a "potentially suspicious or excessive" controlled substance order can be defined as an order "that exceed[s] the permitted quantity by 3 times the normal mean demand" over a 52-week period.[757]

2. In 2013, Janssen modified its definition of suspicious order, stating, "A potentially suspicious or excessive controlled substance order can be defined as an order that exceeds the minimum order quantity requirements, and is above 3x's (300% of) the calculated, 12 month, per weekly order average."[758] Janssen maintained its same suspicious order algorithm from 2006 through at least the date of the deposition of Janssen's Controlled Substances Compliance Director, Michele Dempsey, on March 8, 2019.[759]

3. From 2005 through at least 2018, Janssen has never reported a suspicious order to the DEA.[760]

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[756] *See e.g.,* Acquired_Actavis_01843335 (discussing regulation of entities that refer to themselves as "virtual manufacturers").

[757] *See* JAN-MS-03741170.

[758] *See* JAN-MS-03124101 (Dempsey Deposition Exhibit 37).

[759] *See* Dempsey Deposition at 471:23-472:18.

[760] *See* Dempsey Deposition at 487:2-488:18; *see also* JAN-MS-05444748 at 761 (Dempsey Deposition Exhibit 26 (Janssen's SOM Audit Report, stating, "It appears that the JOM SOM has not reported a suspicious order for controlled substances as suspicious during its entire time in operation.").

4. Janssen only monitored for orders of unusual size and failed to ever monitor for frequency and/or pattern in real-time.[761]

5. Beginning in 2005, Janssen received chargeback data that would have provided visibility into the orders of its opioids by downstream customers.[762]

6. Further, since at least 2011, Janssen's "SCG Trade Group" and its "marketing teams" were using 852 data (wholesalers' inventory and total sales out to their customers) and un-blinded 867 data ("wholesalers total sales out to their customers broken out by outlet, *i.e.*, Retail Pharmacies, Hospitals, Long Term Care, Clinics, etc. Last Points-of-Care in the Supply Chain where product is shipped prior to delivering to the patients"), as well as chargeback data to gain insights into purchasing behavior of individual pharmacies and other customers to resolve demand issues and help build demand strategies.[763] According to Janssen's documents, this information was used by sales and marketing to spot high prescribers and to ensure that wholesalers were stocking targeted pharmacies with Janssen's opioids.[764] Janssen also was buying third party data from Integrichain and ValueTrak.[765]

7. Janssen's Director of Controlled Substances Compliance, Michele Dempsey was asked whether her compliance group was getting stocking data while looking at suspicious order monitoring in 2012. The answer was, "no, we were not."[766] When asked if it might have been useful to see which pharmacies were stocking at a higher volume than others in a given zip code, Ms. Dempsey replied, "No."[767]

8. Janssen never incorporated any of the relevant transactional sales data that could assist in disclosing diversion into its real-time SOM system, including, IQVIA, chargeback data, sales representatives' tips, or even the Integrichain and ValueTrak data that its Trade Analytics team was using in order to sell its opioid products and track stocking at the pharmacy level.

9. In 2012, Janssen Ortho-McNeil's ("JOM") "Customer Service" team was required to use ValueTrak data after a distributor customer's order was flagged as potentially suspicious

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761 *See* Dempsey Deposition at 433:21-455:13.

762 *See* JAN-MS-01117436 at slide 3 ("In 2005, wholesalers began sending us information on their shipments to qualify for Distributor Performance Agreement (DPA). Key information we receive: . . . 844/849 – Chargeback data which identifies how much a vendor qualifies for rebates.").

763 *See* JAN-MS-01117436 at slide 3.

764 *See* JAN-MS-00454956.

765 *See* JAN-MS-01117436.

766 *See* Dempsey Deposition at 106:1-8; 111:14-18.

767 *See* Dempsey Deposition at 114:11-19.

or excessive, and after receive a reason for the increase in demand, only "to show the [distributor] customer's inventory and compare that inventory to the demand of the increase."[768]

10. Ms. Dempsey testified that Janssen only utilized 852 and 867 data from the wholesaler in its order monitoring program, "as needed."[769] However, Ms. Dempsey testified that, in 2017, when she was aware that another division within Janssen was getting third party 852 and 867 sales data, "I don't know if prior to 2017 [the third party data] did include Duragesic and Nucynta. But at the time that I was – I learned of this [third party data], Duragesic was not included, and Nucynta was no longer a product."[770] In my expert opinion, consistent utilization of this third party data to monitor sales of Janssen's Duragesic and Nucynta for orders that should have been flagged for review based upon unusual size, frequency or pattern, certainly was necessary to identify potential diversion when evaluating potentially suspicious orders and should have been used for that purpose.

11. Additionally, through purchases of data from ValueTrak,[771] Janssen stated that "we can now identify the most valuable individual pharmacies in the marketplace."[772] Ms. Dempsey further testified that she was unaware that Janssen was purchasing such third party data until 2017.[773] Ms. Dempsey also testified that she was unaware that Janssen had the "ability to unblind the sales it was making to wholesalers to obtain visibility of [Janssen's] inventory at individual retail stores" until "2017."[774] This data enabled Janssen to know the end customers of its distributors. Janssen was using this information, in addition to monitoring pharmacy inventory, to track the "hot spot markets prescribers writing the higher strengths so [Janssen] can provide that data to the JOM Planners and Wholesaler Buyers."[775] However, Janssen was not incorporating the third party data into its real-time order monitoring platform.[776]

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768 *See* JAN-MS-03124101 at JAN-MS-03124105, section 7.1.6 (Dempsey Deposition Exhibit 37).

769 Ms. Dempsey testified, ". . . when an order, a controlled substance order, goes through the order monitoring program, if it is deemed to be questionable, customer service planning is involved in reaching out to the customer to understand why it is not a typical order. And this data is used to -- in some cases, as justification to show that downstream inventory is low and it required additional information -- this order was justified for release." *See* Dempsey Deposition at 123:11-124; *see also* 122:16-123:9 and 132:18-134:11.

770 *See* Dempsey Deposition at 104:3-16.

771 *See* JAN-MS-00454956; JAN-MS-01117436.

772 *See* JAN-MS-01117436 (844-849 – "Stocking Tool Territory Level: For the first time, our sales reps know which pharmacies have purchased, and which high decile pharmacies have not purchased our products." *Id.* at slide 14 (depicting how Janssen was tracking Nucynta down to the specific pharmacies, such as specific CVS, Walgreens and Wal-Mart locations).

773 *See* Dempsey Deposition at 340:6 – 343:20.

774 *See* Dempsey Deposition at 98:15-99:16.

775 *See* JAN-MS-00454956.

776 *See* Dempsey Deposition at 133:2-134:12.

12. Janssen's SOPs did not cover pharmacies or prescribers. Michele Dempsey testified that she was unaware that Janssen's sales group was doing trend analysis on its higher prescribers of Nucynta and Duragesic. When pressed on whether she would have wanted to know the prescriber data trends in her role, she replied, "No."[777] As above, I believe Janssen should have been using its data and analysis on prescribers to inform its suspicious order monitoring program relative to its due diligence obligations.

Without restating every finding laid out above, I conclude that Janssen's real time order monitoring program only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders, and was set high to effectively identify diversion or suspicious orders. Further, Janssen's Controlled Substances Compliance Director, Ms. Dempsey, confirmed that downstream data was only utilized in "some cases as justification to show that downstream inventory is low. . ." and additionally testified that "during our monthly compliance reviews [which started in 2013] it was presented as a data source that could be used, potentially, to help investigate questionable orders,"[778] but did not know as of 2017 whether the third party included information concerning Nucynta and Duragesic. Further, Janssen's real time order monitoring system did not utilize any downstream customer information available, and did not differentiate among NDC codes for drugs with a higher risk of diversion. The SOM design was not effective in identifying suspicious orders.

C. MALLINCKRODT

Based on the evidence I have reviewed in this case, Mallinckrodt did not maintain effective controls to prevent diversion, failed to design and operate an adequate suspicious order system , and failed to take reasonable steps to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. The record provided to me reveals Mallinckrodt only had draft SOM policies that were continually being reworked and revised from the 2008-2011 time period, and no formal policies before that period.[779] These drafts relied heavily on numeric formulas that initially

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777 *See* Dempsey Deposition at 188:5-189:18.

778 *See*, Dempsey Deposition at 132:2-134:11.

779 The following are the dates and Bates number of the each of the SOM drafts from the 2008-2011 time period:

Date	*Bates number*
2008	MNK-T1_0000273894
2008	MNK-T1_0000268911
2008	MNK-T1_0000419993

only flagged orders [redacted][780]

2. Mallinckrodt effectively only monitored for orders of unusual size and failed to monitor for frequency and/or pattern in real time.[781] (July 8, 2008 Draft Controlled Substance Order Monitoring Policy) (Defining a "peculiar order" as [redacted][782] (Oct. 29, 2010 Identified and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program) (Defining a "peculiar order" as an [redacted][783] (Oct. 18, 2012 Identification, Investigation, and Report of Controlled Substances Suspicious Orders) (Creating a two-tiered system with

2008	MNK-T1_0000296382
2008	MNK-T1_0000263965
2010	MNK-T1_0000264260
2011	MNK-T1_0000264275
2011	MNK-T1_0000264200
2011	MNK-T1_0000259166
2011	MNK-T1_0000571916
2011	MNK-T1_0000264053
2011	MNK-T1_0000264265
2011	MNK-T1_0000264231
2011	MNK-T1_0000264270
2011	MNK-T1_0000264279
2011	MNK-T1_0000264209
2011	MNK-T1_0000259157
2011	MNK-T1_0000264214
2011	MNK-T1_0000264205
2011	MNK-T1_0000259162
2011	MNK-T1_0000259153
2011	MNK-T1_0000264265

780 *See* MNK-T1_0000301994.

781 MNK-T1_0000296382.

782 MNK-T1_0000264260.

783 MNK-T1_0007476261.

tier 1 setting monthly limits on Oxy 15 and Oxy 30 shipments and tier 2 consisting of a "standard algorithm" of [redacted] and (b) [redacted]

3. This formula did not satisfy requirements to detect and investigate suspicious orders. Mallinckrodt's own compliance department noted that the [redacted] potentially allowed customers to evade the system by [redacted] to stay under the threshold.[784]

4. This formula was actually increased to a [redacted] in 2010 (before being [redacted]. The justification for this increase was that a [redacted] was identifying too many orders and placed too much of a burden on the one person at Mallinckrodt responsible for reviewing peculiar orders.[785]

5. If an order did not pass the numeric threshold, it was not subject to further scrutiny, even if there may have been other reasons to be suspicious of the order.[786] Moreover, Mallinckrodt discontinued using any formula from 2008 through 2009. According to Jim Rausch, the Customer Service Manager responsible for investigating peculiar orders, the only check Mallinckrodt appears to have performed during that period was to verify the customer's 222 form, a process that was clearly inadequate.[787]

6. Mallinckrodt did not use appropriate due diligence for those orders that were flagged under Mallinckrodt's formula. In particular, Mallinckrodt inappropriately relied on its sales force, which was compensated, in significant part, based upon the volume of opioids they sold, to determine whether an order should be shipped.[788] According to Karen Harper, Mallinckrodt's compliance head, the marketing and sales force were the compliance

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784 MNK-T1_0000477889.

785 MNK-T1_0000264260.; Harper Transcript at 321 (justifying moving from a [redacted] because the peculiar order report was "too lengthy" and was creating too much of an "administrative burden").

786 Rausch Transcript at 194:3-23 (confirming that if an order was not flagged by Mallinckrodt's algorithm, it was not examined; and acknowledging that if there were gaps or faults in the algorithm, it was possible for problematic orders to get through.) Gillies 30(b)(6) Transcript at 92:7-18 (confirming that only peculiar orders were reviewed and outside of the peculiar order algorithm, there was no separate system or protocol for identifying peculiar orders).

787 Rausch Transcript at 139:14-140:9 (other than verification of the 222 forms Mallinckrodt did not have a suspicious order program in place between fall of 2008 and 2009); MNK-T1_000419956 (email stating "confirmation of the customer's current DEA registration and status and receipt of a DEA 222 form are not alone adequate in determining whether an order is suspicious"); Ratliff Transcript at 242:2-9 (agreeing that it would not be proper to just rely solely on registration status and the 222 form in determining whether or not to ship an order).

788 MNK-T1_0000315995 (excel sheet showing national account managers and bonus payments); Borelli Transcript at 40:22-45:5, 47:17-21.

department's "boots on the ground."[789] In a September of 2010 email, Harper was aware of the conflict and acknowledged that "the actual day-to-day monitoring responsibility should be switched to a non-customer service function in that those that have responsibility to manage the orders have a conflict of interest in deciding which orders should ultimately be shipped – with ultimate right of refusal retained by Controlled Substance Compliance."[790] [791]

7. Mallinckrodt shipped suspicious orders before due diligence was completed. Rausch explicitly warned Karen Harper that "[s]ince I don't hold the orders up during my due diligence it's possible that the order could ship. I thought we discussed this and alerting the DEA about a suspicious order/customer for further investigation would be our process going forward."[792]

8. Furthermore, Ms. Harper admitted that Mallinckrodt did not always perform due diligence on orders before shipping them[793] and that failure to conduct such an investigation would lead to Mallinckrodt potentially shipping suspicious orders.[794]

9. Prior to 2010, Mallinckrodt's SOM program also failed to utilize chargeback data, or any other data available to it, to trace the total amount of Mallinckrodt opioid products being delivered to downstream customers. Mallinckrodt did not formally incorporate chargeback data into its SOM program until January of 2011, and did not start using its chargeback data to systematically review and identify problematic pharmacies until Fall of 2011.[795]

10. More generally, in 2010, Mallinckrodt began identifying through chargeback data pharmacies, pain clinics and physicians (almost all of whom were in Florida) that engaged in the suspicious practice of purchasing controlled substances from multiple Mallinckrodt distributors and wholesalers, but only identified an insubstantial number of suspicious orders to the DEA.

11. In late 2010 Mallinckrodt retained a former DEA employee to review its SOM program. This consultant advised Mallinckrodt that its program was inadequate and recommended changes. Mallinckrodt did not implement many of these changes, and continued its

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[789] Harper Transcript at 59:7-19 (National Account Managers "were our eyes and ears and boots on the ground at the customer accounts.).

[790] MNK-T1_0000280260.

[791] *See e.g.*, MNK-T1_0000274737, MNK-T1_0000289692, MNK-T1_0000298653, MNK-T1_0000298795, MNK-T1_0000267906, MNK-T1_0000267896, MNK-T1_0000290934, MNK-T1_0000369397 (collecting examples of NAM involvement in SOM process).

[792] Harper Transcript 199-203:17

[793] Harper Transcript at 200:4-10.

[794] Harper Transcript at 203:1-17.

[795] MNK-T1_0000289368 (Letter to distributors identifying pharmacies subject to chargeback denials); K. Harper Deposition 400:11-401:10.

exclusive reliance on a numeric formula for identifying peculiar orders. See Paragraph 2 above. Mallinckrodt deleted questions from its Distributor Questionnaire regarding the distributors monitoring of their customers.[796]

12. Prior to 2008, Mallinckrodt identified nationwide, at most, a total of 25 suspicious orders to the DEA. From 2008 through 2011, Mallinckrodt identified, at most, a total of 9 suspicious orders to the DEA. This is despite numerous orders being flagged for exceeding Mallinckrodt's numeric formula.[797]

13. Despite having access to chargeback data and following press reports identifying problematic distributors, as well as internal emails expressing concerns with shipments to Florida, Mallinckrodt continued to ship its opioids to distributors that ultimately had their licenses revoked or suspended by the DEA for the diversion of prescription drugs.[798] Furthermore, Mallinckrodt failed to conduct adequate investigations and audits of its wholesale distributor customers.[799]

14. There are numerous examples of significant quantities of Mallinckrodt opioid products going to physicians that are now serving lengthy prison sentences for the illegal dispensing of opioids. These included Dr. Barry Schultz (serving a 157 year sentence for opioid trafficking and manslaughter); Dr. Shehta (suspended by the DEA after purchasing 451,700 UOM of oxy 15 and oxy 30s from Sunrise); Dr. Shook (Mallinckrodt's leading purchaser of oxycodone and sentenced to four years in prison for illegally prescribing opioids).[800] That these doctors were receiving Mallinckrodt products was not news to Mallinckrodt because its chargeback database contained information on all of these doctors and the amount of Mallinckrodt opioids they received. In fact, Karen Harper directed the compliance department to prepare reports cross-referencing pill mills identified in news articles against Mallinckrodt's chargeback database.[801] Referred to as "indirect match reports," these reports identified specific sales to pills mills, allowing Mallinckrodt to

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[796] See MNK-T1_0000368388 (Email from K. Harper to G. Collier and K. Muhlenkamp (8/26/10)).

[797] March 4, 2019 Mallinckrodt Response to Interrogatory No. 32 and Exhibits cited therein.

[798] MNK-T1_0002077756 (summarizing DEA concerns about volume of Oxy 15 & 30 mg tablets being shipped to Florida and noting that DEA believes that a significant percentage of Mallinckrodt products are being diverted); MNK-T1_0000562325 (email discussing notice from law enforcement that Mallinckrodt product had been diverted from Florida to Tennessee and recommending an immediate audit of the distributor); MNK-T1_0000386857 (email regarding Grand Jury Report and article about the crackdown on Florida pill mills); MNK-T1_0000279166 (email noting multiple law enforcement inquires in Florida and surrounding states relating to a Mallinckrodt distributor); MNK-T1_0000384265 (email from customer service rep to sales executive asking if he "heard anything about Oxycodone in Florida, and why there are so many people from Kentucky going to Florida to get their prescriptions filled?").

[799] Harper Transcript at 415:12-417:16.

[800] *See* Borelli Transcript at 161:23-169 (Dr. Shook); 170:24-172 (Dr. Shehta); and 176:12-177:5 (Dr. Schultz).

[801] *See* MNK-T1_0000283880.

determine the exact amount of its products that were likely diverted.[802] While these reports were used to make after-the-fact determinations that their product was diverted, chargeback data was not used to prevent diversion, despite Mallinckrodt's clear awareness of the available of the data and its potential uses.

15. The above conclusions are further confirmed by the fact that Mallinckrodt has admitted, in a Memorandum of Agreement with the DEA, that from 2008-2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 2, 2006 and December 27, 2007."[803]

Without restating every finding laid out above, I conclude that Mallinckrodt used an SOM system with a threshold based trigger, which was then increased in order to avoid identifying suspicious orders. It only looked for orders of unusual size and not for frequency and/or pattern in real time. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The system did not utilize downstream customer information available, did not differentiate among NDC codes for drugs with a higher risk of diversion. Nor did Mallinckrodt conduct adequate due diligence on suspicious orders, and left clearing suspicious orders to sales personnel with clear financial conflicts of interest, which Mallinckrodt recognized. Mallinckrodt also failed to stop shipment of suspicious orders. The SOM was not effective in identifying or preventing shipment of suspicious orders.

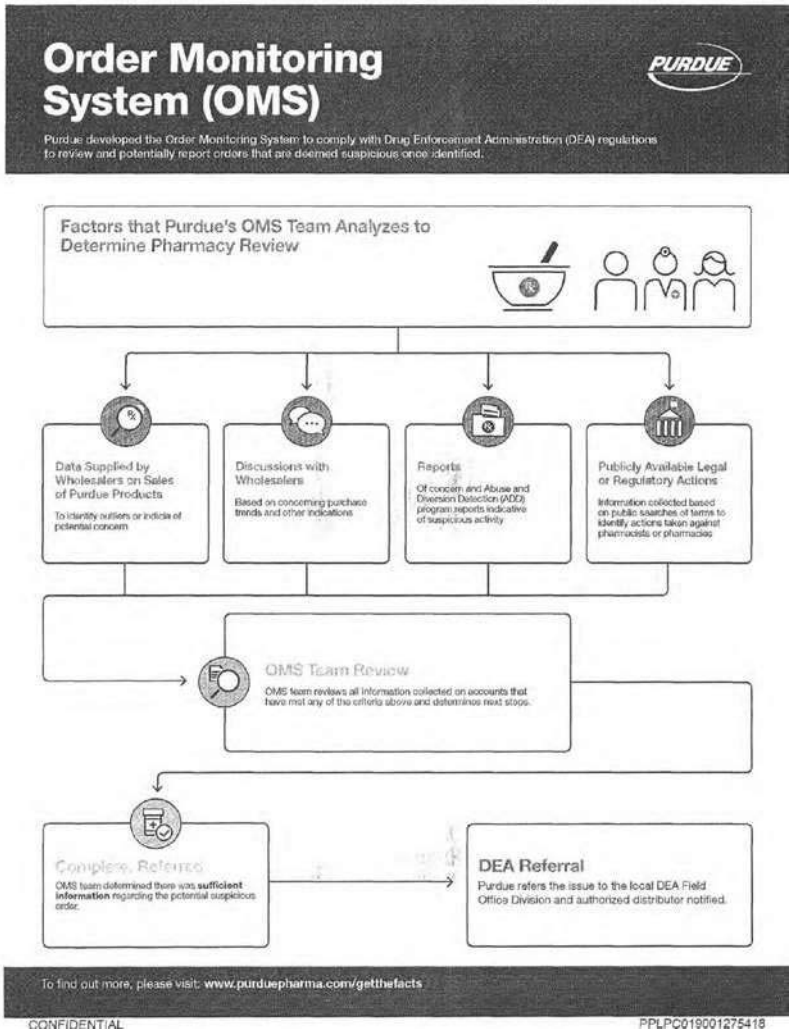
D. PURDUE PHARMA

Based on the evidence I have reviewed in this case, Purdue Pharma did not maintain effective controls to prevent diversion, and did not maintain an adequate SOM program and failed to take reasonable steps to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. Purdue designed an Order Monitoring System that recognized its obligations to comply with DEA regulations to review and potentially report orders that are deemed suspicious when identified. The Purdue OMS system (Purdue schematic below) is a compilation of several different standard operating procedures (SOPs) from various departments within Purdue.

[802] *See* MNK-T1_0000283884.

[803] *See* Depo. of William Ratliff, Ex. 41 (Administrative Memorandum of Agreement").



2. Purdue implemented a series of SOPs intended to explain in detailed steps the various components of its suspicious order monitoring system. The SOPs (and their updates) that relate to Purdue's OMS are 7.7, 1.14, 65, 007, 1.7.1, 001, CC-SOP-000017, CC-SOP-000018, and CC-SOP-000019.

3. In February 2000, Purdue acknowledged its obligation under the Controlled Substances Act to have a "system in place which will disclose suspicious orders of controlled substances to Purdue personnel."[804] Purdue stated specifically, "[w]e are required by the DEA to have such a system in place."[805] From day one, Purdue was primarily concerned with the effect that such a system would have on its relationships with its "customers" (various distributors). One problem that was identified early on was the fact that Purdue "would be reviewing a large percentage of our orders under these guidelines." The reality,

[804] PPLPC004000119321

[805] *Id.*

as realized by Purdue's National Accounts department, was that any review of an order "would be well after the shipment." Purdue's position was that "National Accounts primary function is to sell, not police orders."[806] This attitude was borne out through the years via a practice of rapid approvals of orders of unusual size, frequency, and dollar amounts prior to shipment.[807]

4. **Purdue's SOP 7.7** required the Senior Manager of Customer Service, the Senior Director of Finance Operations, or the Director of Credit Services to review all suspicious orders identified pursuant to SOP 7.7. It required Purdue to inform the field division office of DEA of suspicious orders when discovered. Final reports and recommendations were placed in Purdue's "customer's credit file" as well as being copied to 4 separate Purdue executive officers.[808]

5. Despite clear recognition of the limitations of SOP 7.7, in responding to questions from the NJ Field Division of the DEA regarding the adequacy of Purdue's SOM efforts in January 2006, Purdue identified SOP 7.7 as the mechanism by which Purdue "would determine a suspicious order."[809] Purdue represented to the DEA the following:

> "During the ordinary course of business, members of the Controlled Substances Team in Customer Service are familiar with customer order frequency, order quantities, and dollar amounts. They review each order for unusual quantities or any other deviation from the customers regular order pattern. If any deviations are found, the Customer Service Representative will submit the customers purchase order to the Senior Manager of Customer Service or the Senior Director of Finance Operations for further review. The company business officials then conduct a further internal review process. If the order appears to be suspicious the information is provided to the Associate General Counsel and the Executive Director of CSA Compliance. A determination will then be made if further investigative steps are required and if the findings should be reported to the appropriate Field Office of the DEA."[810]

The extensive layering system described above created a regime in which an incoming suspicious order would have to be evaluated on four different levels before being determined to be "suspicious," despite the fact that it had been flagged as suspicious by Purdue's Customer Service Representative.

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[806] National Accounts further laid out the limitations inherent in Purdue's earliest version of an Order Monitoring System in PDD8801146346.

[807] See generally PPLPC004000207529, PPLPC004000207523, PPLPC004000215590, PPLPC004000213649, PPLPC004000214875, PPLPC004000218107; Deposition testimony of Stephen Seid Vol. 2, 12/13/2018 at 314:20.

[808] PPLPC004000119321.

[809] PPLPC020000057781 at 792.

[810] *Id*.

6. Purdue's files contain numerous examples of orders received by National Accounts from authorized distributors that were deemed suspicious because they exceeded the size of prior orders from the same distributor. These orders were approved, sometimes within minutes, without any serious review of the underlying "suspicious" order.[811]

7. **SOP 1.14** documents Purdue's quarterly Fee for Service Credit Process.[812] Purdue had 17 wholesalers under agreement in 2013.[813] Fee for Service Agreements [FFS] and their counterparts, Distribution Service Agreements [DDSA] describe the calculations made by Purdue each quarter to provide chargebacks and rebates by Purdue back to each wholesaler.[814] The DDSA and/or FFS appear to be separate contracts (with slightly different percentages in each) with respect to each authorized Purdue distributor.

8. Under the terms of the DDSA and/or FFS, Purdue's distributors were paid to provide chargeback data, which is data that specifically traces the sale and distribution of Purdue's product from its authorized distributors to each individual pharmacy, dispenser or other outlet. Purdue utilized a third-party software called ValueTrak (previously Edge Dynamics) to perform the analytics for the chargeback data.[815][816] This chargeback data identifies the Purdue product delivered to every retail pharmacy, outlet and/or dispensary by Purdue's authorized distributors. This data provides Purdue with visibility with respect to the size, pattern and frequency of most orders delivered to each and every pharmacy or other outlet.

9. **SOP 007**, which was first instituted in 2009, developed an Order Monitoring System to review the above described chargeback data as well as IMS/IQVIA and other prescription, pharmacy and prescriber data available to Purdue. [817] The data was collected into the OMS database, which had the capacity to accept notes on the pharmacies under investigation by the committee. I am informed that information from the OMS database could also be generated into a report, and those reports were discussed at OMS committee meetings, typically scheduled every quarter, overseen by Purdue's General Counsel's Office.[818]

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[811] Seid deposition at 314:20-318:18 and related exhibits.

[812] PPLPC004000344799.

[813] Id. at 4809.

[814] Purdue's contractual arrangement with Walgreens was slightly different and styled as an "Inventory Data License Agreement." Under the un-signed versions of the agreements that we have, Walgreens would provide to Purdue, as a licensee, 852 and 867 distribution center data (daily data provided on a weekly basis) as well as store level 852 (data provided on a daily basis) for a fee. See generally PPLPC004000254710; PPLPC004000320062.

[815] Deposition of Stephen Seid (Fact Deposition), 87:10-88:2; 138:15-139.
[816] *See generally* deposition testimony of Stephen Seid Vol. 2, 12/13/2018.

[817] PPLPP003430436.

[818] PPLPC041000014663.

10. The OMS SOP 007 included the creation of an OMS Committee overseen by the General Counsel's office at Purdue beginning in 2009 and then moving to Corporate Security's oversight some years later. The OMS committee is currently inactive and suspicious monitoring duties are carried out pursuant to three new SOPs CC-SOP-000017, SOP CC-SOP-000018 and SOPs CC-SOP 000019 under the supervision of Corporate Ethics and Compliance committee, which from 2009 through September 2017 included approximately seven members.[819]

11. Pursuant to SOP 007, suspicious orders would by flagged as a result of algorithms applied to the chargeback data received from Purdue's authorized distributors concerning approximately 35,000 to 45,000 pharmacies each year, dispensers and other outlets. Members of the OMS committee could change the algorithms.[820] At best, pursuant to the OMS database, only 1,567 orders were identified for investigation over 8 years. Of those investigated, it appears that as of 2012, 365 were reported to DEA.[821] Of the 365, 290 were reported in May of 2011 in an attempt to market OxyContin's new "tamper-resistant" formulation. Those 290 pharmacies had actually ordered less OxyContin that the years before.

12. Purdue has no limitation with respect to the amount of time a suspicious order investigation can remain open and unreported to DEA. In addition, there is no requirement for any investigative material to be in writing. Members of the OMS share what they learn with each other and the General Counsel's office, but there is no requirement that any findings be memorialized in writing.[822]

13. Purdue, at least through September 2017, kept no consistent record of suspicious pharmacies or other entities referred to DEA as suspicious. Mr. Geraci, Senior VP of Compliance and a longstanding member of the OMS testified that the only way such referrals could be identified was to undertake a search of email files of individuals tasked with reporting duties.[823]

14. Purdue had data available to match suspicious prescribers with suspicious pharmacies but failed to refer either the prescribers or the pharmacies to DEA.[824]

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[819] PPLPC012000378037; Depositions were taken of OMS committee members Stephen Seid, Jack Crowley and Frank Geraci.

[820] *See* 30(b)(6) Deposition of Frank Geraci, Apr. 4, 2019, Rough Tr. 179:2-183:20.

[821] PPLPC012000378037

[822] Geraci Rough Tr. 55:16-57:5..

[823] Geraci Rough Tr. 53:12-57:5.

[824] Geraci Rough Tr. 131:3-146:11.

In sum, I conclude that Purdue did not maintain effective controls against diversion, failed to implement a reasonable SOM program, and failed to take reasonable steps to prevent their products from being diverted. In addition to my opinions above, it is my opinion that Purdue failed to keep DEA referral records in an organized and retrievable way making it difficult if not impossible for Purdue to utilize historical data to identify suspicious pharmacies, pharmacists, prescribers or other dispensaries. Purdue failed to use consistent algorithms and failed to investigate the suspicious orders identified by the algorithms. The algorithms Purdue did use were rigid and did not satisfy DEA requirements to detect and investigate suspicious orders. Purdue failed to clearly define a time limit for suspicious investigations to continue before DEA referral and otherwise allowing investigations to continue indefinitely. Purdue failed to adequately utilize ADD reports[825], ROCs[826], Region Zero lists[827], and other indicia of abuse and diversion. Purdue failed to maintain an OMS database that could not be overwritten nor keep a record of queries. Purdue's most recent OMS SOPs continue to exhibit the same flaws as the previous SOPs.

E. ENDO

Based on the documents and testimony I have reviewed, Endo—like the Qualitest and Par entities that I am informed Endo acquired in 2010 and 2015[828], respectively—did not maintain effective controls against diversion, failed to implement a reasonable SOM program, and failed to

[825] **SOP 1.7.1 (2002, 2015)** Abuse and Diversion Detection Program (ADD) "is designed to ensure that interactions with Prescribers and Pharmacists, that reveal observations or circumstances that suggest potential concerns, generate appropriate review and follow up."[825] The policy established an internal procedure at Purdue for implementing the ADD program and it provided specific examples of observations and circumstances that warrant review and follow up through submission of an ADD Report. This policy also requires the Corporate Compliance Department to audit and review sales representatives' call notes to evaluate compliance with this ADD policy.

[826] **SOP 000001.0 (ROC) (2005, 2009)** concerns the routing of Reports of Concern Regarding PPLP Marketed Opioids by field personnel at Purdue Pharma and all associated companies.[826] The SOP does not apply to adverse events, but are defined as "an alleged specific occurrence of abuse or diversion of a PPLP Marketed Opioid Analgesic. Any reports were sent to Drug Safety and Pharmacovigilance Department (DSP) and then DSP forwarded any material they believe contains a ROC to Risk Management

[827] **SOP 65** required that there be a system in place to identify and handle possible cases of abuse and diversion. Purdue's Sales Administration Department had access to prescriber information through IMS/IQVIA. Per SOP 65, on a monthly basis, a list of the top 200 prescribers of selected products was to be generated for review, including a report of the outliers. The top 200 were selected based on the total number of prescriptions written in the previous 12 months. The General Counsel's office would then decide what, if any, further action would be taken. A sample list was attached to this SOP (with attachments A-F). Attachment A stated that doctors who can continue to be called on are printed in RED and doctors that cannot be called on nor can representatives receive commission are in BLUE and known as REGION ZERO.

[828] Endo's acquisition of Qualitest (Endo Press Release, 9/28/2010. "Endo Pharmaceuticals Announces Agreement to Acquire Qualitest Pharmaceuticals for $1.2 Billion." Accessible at http://investor.endo.com/news-releases/news-release-details/endo-pharmaceuticals-announces-agreement-acquire-qualitest; P. Campanelli Tr. 30:21-31:4) and Par (Endo Press Release, 9/28/2015. "Endo Completes Acquisition of Par Pharmaceutical and Provides Financial Guidance." Accessible at http://investor.endo.com/news-releases/news-release-details/endo-completes-acquisition-par-pharmaceutical-and-provides; P. Campanelli Tr. 31:13-15).

take reasonable steps to prevent its products from being diverted. This conclusion is borne out by the documentary and testimonial evidence in this case, as further detailed below:

1. I am informed that Defendants Endo Pharmaceuticals, Inc. (together with Endo Health Solutions, Inc, "Endo") and Par Pharmaceutical, Inc. (together with Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceuticals Holdings Inc., "Par") develop, manufacture, market, distribute, and/or sell prescription opioid products.[829] Endo affiliate Qualitest manufactured opioids both before and after Endo acquired it in 2010. Par also manufactured opioids before and after it was acquired by Endo in 2015. In 2015, Qualitest's operations were combined with Par. Endo now sells branded products, while Par sells generics and/or non-promoted products.[830]

2. Although Endo is not a DEA registrant, in connection with its interactions with both DEA and FDA, it has represented that it would monitor orders and distribution of opioid products for signs of diversion, including suspicious orders.[831] The witness designated by Endo to provide testimony on behalf of Endo on SOM issues affirmed that Endo understood that it had a responsibility to maintain effective controls against diversion for orders of its opioid products.[832]

3. At all times, Endo's internal order review system was carried out by employees in commercial/customer service departments, not by compliance staff that were independent from the sale of the product.[833]

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[829] Endo Press Release, 6/23/2006. "Endo Press Release, "Endo Receives FDA Approval for Opana ER (oxymorphone HCl) Extended-Release and Opana (oxymorphone HCl) Immediate Release Tablets CII." Accessible at: http://investor.endo.com/news-releases/news-release-details/endo-receives-fda-approval-opanar-er-oxymorphone-hcl-extended) [Charachterizes the Opana NDA as "internally developed"]; S. Macrides Tr. 40:6-41:8; ENDO-OPIOID_MDL-04927196 generally; ENDO-CHI_LIT-00547005 generally; S. Macrides Tr. 40:6-22; S. Macrides Tr. 40:6-22.

[830] Depo. of P. Campanelli, 32:8-18; Depo. of Macrides, 81:1-17; 81:23-82:12, 16-17.

[831] Endo met with the DEA to brief the agency on Endo's risk management plan to prevent diversion of oxycodone ER. *See* 2003.9.30 DEA ENDO Meeting ENDO- OPIOID_MDL-00451334. This was following the announcement of the DEA's action plan to prevent diversion and abuse of OxyContin (which also mentioned a long history of abuse of Endo's Percocet and Percodan oxycodone combination products). 2003.7.14 DEA Action Plan to Prevent Diversion, ENDO-OPIOID_MDL-01692317. Endo assured the DEA Endo would "monitor for signals of diversion" of generic OxyContin, and noted that, although Endo could not "predict what that signal will look like," Endo was "committed to working with the DEA and law enforcement agencies as appropriate" ENDO DEA Meeting Minutes, p.2 ENDO-OPIOID, MDL-01706007. Endo made similar representations to FDA in a "RiskMAP" put in place in connection with Endo's launch of Opana ER in 2006. ENDO-CHI_LIT-00234542. The RiskMAP represented that "[a]s for all of Endo's controlled substance products, the manufacturing and distribution chain is highly controlled and closely monitored," including "order management practices" that allegedly "monitored [order data] frequently to look for unusual changes in deliveries to customers." *Id.* at § 3.4 and Appendices 2 & 3.

[832] S. Macrides Tr. 94:5-21

[833] L. Walker Tr. 53:1-54:10; ENDO-CHI_LIT-00234542.

4. Until at least 2014, Endo never conducted any due diligence with respect to the customers to which it was selling its opioids beyond confirming the customer held a DEA registration.[834] In testimony, Endo asserted that it relied on due diligence and site visits conducted by Qualitest/Par, but testimony from representatives of Qualitest's head of DEA compliance from 2011 through 2014 indicates that Qualitest had no responsibility for Endo's SOM process or associated due diligence. [835]

5. Until at least 2013, Endo's internal order review system was a "limited" system using a rudimentary algorithm that did not monitor for orders of unusual quantity, size, or frequency.[836] The process was designed only to identify "excessive" orders from a commercial perspective, rather than suspicious orders based on unusual volume, frequency or pattern. Specifically, in 2013, Ms. Walker stated:

> In Endo's SAP system, we have a limited SOM Program that looks at our buying (wholesalers) customers' 3 month and 12 month history and if any order is above the 3 or 12 month it goes on hold until it is reviewed by Customer Service.[837]

Beginning in 2014, Endo expanded its algorithm for identifying suspicious orders to include three order characteristics—quantity, size, and frequency—by class of customer trade. [838] However, despite tens of thousands of order line items for controlled substances having been flagged under this and predecessor order systems, no suspicious orders were ever reported to DEA by Endo or UPS for Endo products at any point in time. S. Macrides Tr. 103:19-109:5; L. Walker Tr. 67:4-68:7.

6. Endo never examined chargeback data as part of its internal order review process for

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[834] Prior to 2014, Endo conducted no due diligence on its customers or customers' customers. Walker Tr., 633:18-635:21. In 2014, Endo was aware of a duty to perform such due diligence. ENDO-OPIOID_MDL-05968962. Endo inquired whether UPS (Endo's third party order fulfiller) could carry out this due diligence on its behalf. PAR_OPIOID_MDL_0000369517. But UPS made clear that it could not carry out Endo's "know your customer" duties. PAR_OPIOID_MDL_0000369517. Additionally, UPS noted in its own November 2009 SOM Summary that due to UPS's lack of a direct contact with its clients' (like Endo) customers, UPS is unable to conduct routine customer questionnaires, on-site visits, or ensure legitimate use of controlled substance products. UPSSCS0007432. Endo's corporate designee confirmed that the "know your customer" obligation was an Endo obligation. S. Macrides Tr. 544:14-545:14.

[835] T. Norton Tr. 346:13-18.

[836] EPI000620553

[837] *Id.* at EPI000620553

[838] ENDO-OPIOID_MDL-05969985; It does not appear that Endo ever had any SOM-specific SOPs. L. Walker Tr. 300:23 – 309:24. Ms. Walker did identify a 2015 SOM Program Summary (ENDO-OPIOID_MDL-059482), but that document does not contain any "Standard Operating Procedure." Notably, a master list of Endo's company-wide SOPs did not contain any SOM SOPs or DEA Compliance procedures, at least as of 2012. ENDO-OPIOID_MDL-05950068.

its branded opioids. As of December 2018, Endo's order review system did not utilize chargeback or IMS/IQVIA data, and relied on Qualitest and later Par to perform site visits and due diligence.[839] However, the former head of DEA compliance for Qualitest, Tracy Norton, testified that her group had no responsibility for Endo's branded business.[840] Ms. Walker also testified that Endo never conducted site visits of its customers or its customers' customers.[841]

7. Endo's internal order review system never resulted in any order of an Endo opioid being reported to the DEA and Endo never blocked shipment of any opioid order based on its internal reviews, despite orders being flagged for review by Endo's systems.[842]

8. An August 2008 audit by a DEA consultant found that Qualitest's system for reporting suspicious orders to DEA needed improvement to comply with regulatory requirements—particularly with respect to information needed for decisions about whether or not to ship an order.[843] Additionally, from 2008-2015, Qualitest was the subject of several DEA investigations, letters of admonition, civil penalties, and enforcement actions.[844] Among other things, the DEA found Qualitest records could

[839] L. Walker Tr. 190:1-190:13, 164:9-174:17.

[840] T. Norton Tr. 343:18-346:18.

[841] L. Walker Tr. 635:1-9.

[842] In the fall of 2013, Endo and Qualitest audited the UPS SCS SOM program. PAR_OPIOID_MDL_0000404095; L. Walker Tr. 586:15-590:4. Among other things, the internal audit found that, as of February 2013, UPS SCS had not reported any Endo/Qualitest product orders as "suspicious orders" to any agency, did not visit customers, lacked the functionality to visit or know customers' customers, and did not utilize chargeback data, trending analyses, or modify its program based on current diversion trends. PAR_OPIOID_MDL_0000404285; PAR_OPIOID_MDL_0000404095 (noting "items identified *as concerns* during the audit are classified below as E/Q or UPS") (emphasis added); *see also* PAR_OPIOID_MDL_0000376972, p. 9 ("gaps identified" in UPS SCS program). See also UPS DEA Non-Prosecution Agreement, Mar. 29, 2013, available athttps://www.justice.gov/sites/default/files/usao-ndca/legacy/2013/03/29/UPS.%20signedNPA.pdf

[843] PAR_OPIOID_MDL_0000076010.

[844] DEA Enforcement Actions Include: 1) Sept. 25, 2008 DEA Investigation of SOM Handling & Procedures PAR_OPIOID_MDL_0000399716; 2) Sept. 24, 2010 DEA Letter of Admonition for Generics Bidco Violations with Sept. 30, 2010 QT Response to DEA Letter of Admonition PAR_OPIOID_MDL_0001615738; 3) Sept. 27, 2010 DEA Notice of Intent to Serve Civil Penalties for Violations of the Controlled Substances Act PAR_OPIOID_MDL_0002102288; 4) Feb. 15 2011 QT MOA with Alabama US Attorney & $15,000 Fine PAR_OPIOID_MDL_0002102288 (failed to maintain complete and accurate records and inventories of controlled substances imported and/or received in violation of federal statute and regulations); 5) Nov. 2011 DEA Charlotte Inspection PAR_OPIOID_MDL_0000390035 (DEA discussed SOMS requirements at length and the initial inspection that led to Mar. 2013 SOMS meeting); 6) July 10, 2012 QT DEA Deficiency Letter (for failure to maintain adequate security and storage of controlled substances or keep accurate accountability) and Aug. 10, 2012 QT Response to Deficiency Letter ENDO-OPIOID_MDL-02827463 ; 7) Nov. 27, 2012 DEA Quota Meeting PAR_OPIOID_MDL_0000369261; 8) Mar. 6, 2013 DEA QT SOM Meeting PAR_OPIOID_MDL_0001647888 (internal DEA Meeting Minutes found QT had Inadequate SOMS); 9) Oct. 17, 2013 Follow-Up DEA Meeting for Briefing on Compliance Efforts/Changes re SOMS ENDO-OPIOID_MDL-01448683; 10) Sept. 30, 2014 Qualitest DEA Notice of Intent to Serve Civil Penalties for CSA Violations PAR_OPIOID_MDL_0001059825 (relating to inaccurate recordkeeping & egregious inventory discrepancies) and Dec. 31, 2014 QT Settlement Discussion

not account for, and had deviations of, at least 9 million pills for the period of December 31, 2012 through July 14, 2014.[845]

9. As late as March 2013, Qualitest's SOM process had multiple deficiencies, including:

   i. Qualitest applied SOM only to "retail" customers;[846]

   ii. Orders were only on the basis of "historical purchases by an individual customer (thresholds),"[847] and not by size pattern or frequency as required by 21 CFR 1301.74;[848];

   iii. Qualitest did not evaluate chargeback data for SOM[849];

   iv. Qualitest did not conduct rigorous due diligence of its customers or customers' customers;[850] [851]

   v. Qualitest's site visits and due diligence were carried out by sales personnel, not compliance staff.[852]

10. At least as late as June 2009, Qualitest personnel "cut" orders down in size and just increased the number of orders, so that each smaller order would clear Qualitest's SOM "thresholds," without reporting the size of the original single order to the DEA as

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Response. PAR_OPIOID_MDL_0002108008 (noted new SOPs and SAP system they were implementing to fix issues DEA identified in their inventory & record keeping of controlled substances); 11) Feb. 18, 2015 QT MOA with Alabama US Attorney & $300,000 Penalty PAR_OPIOID_MDL_0002102254; 12) Sept. 10, 2015 DEA Letter of Admonition for Manuf. QT/Vintage Pharmaceuticals CSA Violations ENDO-OPIOID_MDL-02879035 and Sept. 29, 2015 QT Response to DEA Letter of AdmonitionENDO-OPIOID_MDL-02879037.

[845] PAR_OPIOID_MDL_0001059825.
[846] PAR_OPIOID_MDL_0000363469

[847] PAR_OPIOID_MDL_0001647888

[848] PAR_OPIOID_MDL_0001647888; PAR_OPIOID_MDL_0000373333; PAR_OPIOID_MDL_0000018920; T. Norton Tr. 301:11-302:2

[849] PAR_OPIOID_MDL_0001647888; T. Norton Tr. 71:12-73:5

[850] PAR_OPIOID_MDL_0001647888 (During the meeting with FDA Norton stated that Qualitest did not conduct "routine" visits to customers or customers' customers); T. Norton Tr. 232:1-13 (Norton was "unaware" of any due diligence files created as a result of customer visits prior to 2013)

[851] In October 2013, Qualitest wrote to its customers explaining that Qualitest was changing its SOM process to include confirmation that customers had suspicious order monitoring practices in place to ensure legitimate use of their products. In its letter, Qualitest acknowledged it had a duty to conduct its business as a "responsible corporate citizen" and, therefore, "to do as much as we can to prevent drug abuse and diversion in our communities.do everything possible to prevent diversion, and that the failure to have "adequate controls in place to discourage and prevent the diversion of prescription products" can lead to prescription opioids leaving "legitimate channels," with "heart-wrenching consequences" for the community. ABDCMDL00337067.

[852] PAR_OPIOID_MDL_0001647888

suspicious.[853]

11. The due diligence process Qualitest implemented in late 2013 was not applied conscientiously or consistently. For example, large "Tier 1" customers' orders could not be reported or stopped as suspicious through the process that applied to other customers, but were instead routed to the Chief Operating Officer.

12. Qualitest's implementation of its new standards was not robust, and overlooked diversion risks for its biggest customers. For example, even when proper policies were lacking and raised concerns, Qualitest continued to seek ways to work with the customer, rather than terminating the relationship.[854] It was only when Qualitest began looking at chargeback data that Qualitest found problematic secondary customers and actually reported them to DEA. Likewise, Qualitest did not report or cease distribution for any of its biggest customers or their customers. Par's 3/4/19 Response to Plaintiffs' Interrogatory No. 32. Indeed, Qualitest's SOM Advisory Board, established to determine appropriate action on SOM issues, did not have the authority to terminate "Tier 1" customers, i.e. a customer with a minimum of ten million dollars in overall sales and/or 750,000 dosage units of controlled substances or List 1 chemical purchases annually; such action was left to the discretion of the Chief Operating Officer.[855]

13. At least as early as 2010, Par was selling opioid products,[856] but, according to an outside audit, had no SOM program.[857]

After Endo acquired Par in 2015, internal documents confirmed that Par's order review process still had major deficiencies, including: SOM decisions made by sales or customers

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[853] Specifically, the 2009 Qualitest SOM audit review found: "The review of Order Release Requests showed that many requests were made for quantities of drugs that were several times greater than the current limit set in the order monitoring system. In most of those instances, the size of the order was cut down and the order was approved to be released, with some increase to the limit in the Order Monitoring System. Although the original order requested a quantity of controlled substances that was larger than QT was willing to ship to the customer, no report of a suspicious order was sent to the DEA as required by 21 CFR 1301.74(b). Each Order Release Request that is rejected or modified by QT should be sent to DEA as a suspicious order. Sending these orders to DEA will document to DEA that QT is monitoring the orders on a continuing basis and is monitoring controlled substance orders in a reasonable manner." *Id*. at PAR_OPIOID_MDL_0000398177. *See also* . PAR_OPIOID_MDL_0000398174.

[854] *E.g.*, PAR_OPIOID_MDL_0000020898 (March 19, 2014 report by Qualitest Manager, Customer Due Diligence & SOM expressing "concern with the current program" used by Preferred Pharmaceuticals); ENDO_HSGAC_0010368 (October 2014 emails concerning ongoing communications between Qualitest and Preferred Pharmaceuticals concerning Preferred Pharmaceuticals' very informal SOM program).

[855] PAR_OPIOID_MDL_0001642692.

[856] *See* Par 3/4/2019 Response to Plaintiffs' Interrogatory No. 33, Exhibit A (reflecting sales, for example, of Chlorphen/Hydrocodone (in 2010), Morphine Sulfate ER (beginning in 2012), and Oxycodone (beginning in 2014).

[857] Review of Par's DEA compliance found "There is no Suspicious Order Monitoring program in place." PAR_OPIOID_MDL_0001053153.

service rather than regulatory employees, no customer due diligence other than confirming a DEA license, no reliable review for size, pattern or frequency and an SOP that only required reporting "criminal" activities to the DEA, which "misse[d] the point of the regulations," which is that, "suspicious orders should be reported as soon as they are identified."[858] Furthermore, there were no SOMS staff and the SOMS function was limited to a manual review conducted by sales personnel, which was "viewed as a conflict of interest by the DEA,"[859] After the Par-Endo merger, the former elements of the QT DEA compliance unit took responsibility for SOMS for both businesses.[860]

In sum, I conclude that Endo, Qualitest, and Par did not maintain effective controls against diversion, failed to implement a reasonable SOM program, and failed to take reasonable steps to prevent their products from being diverted. Endo employed a rigid "excessive orders" system operated by sales and commercial personnel, never looked to available data on its customers' customers, and failed to conduct any meaningful due diligence of its customers. Until at least the spring of 2013, Qualitest applied SOM review only to "retail" customers, used a rigid formula that did not examine orders for unusual size, frequency, or pattern or account for class of trade, ignored available data on its customers' customers, and failed to conduct any meaningful due diligence. After the spring of 2013, Qualitest's SOM program lacked real rigor, independence, and consistency. Par had no effective, independent SOM program prior to 2015 and, thereafter, operated under the deficient program Qualitest used. None of these entities employed an SOM or order review program that was an effective control against diversion.

F. TEVA

I am informed that Teva Pharmaceuticals Industries, Ltd. ("Teva Ltd.") sells and distributes name-brand and generic opioid pharmaceutical products through the following United States subsidiaries:[861]

- Teva Pharmaceuticals USA, Inc. ("Teva USA"), which sold and continues to sell generic opioids pharmaceutical products at least since 2006.[862]

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[858] PAR_OPIOID_MDL_0001596366

[859] PAR_OPIOID_MDL_0001024034.

[860] *Id.*

[861] Depo. of Hassler, 34:11-43:19, Exhibit 4.

[862] I am informed Teva is the ANDA holder for generic Vicoprofen (hydrocodone bitartrate and Ibuprofen tablets; ANDA 076023) which was approved by the FDA on April 11, 2003. Additionally, I am informed Teva acquired Barr Pharmaceuticals in 2008, and Barr was the ANDA holder for generic Demerol Tablets (meperidine hydrochloride tablets; ANDA 088639), which was approved by the FDA on July 2, 1984. Moreover, Barr received a license from Cephalon to sell generic Actiq, which became effective September 5, 2006. (*see Cephalon, Inc. v. Barr Labs., Inc*., 389 F.Supp.2d 602 (2005)) Therefore, it appears Teva and its predecessor entities may have sold generic opioids prior to 2006. *See also*, Depo. of Hassler, 217:17-218:6.

- Cephalon Inc. ("Cephalon"), which Teva Ltd. acquired in 2011, and which sold and continues to sell Actiq and Fentora, two name-brand Transmucosal Immediate-Release Fentanyl products approved by the FDA in 1998 and 2006 respectively.[863]
- Watson Laboratories, Inc., Actavis, LLC, and Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) ("Actavis Generic entities"), which Teva Ltd. acquired from Allergan plc in 2016 as part of its acquisition of Allergan's global generic pharmaceutical business for $40.5 billion, and which sold and continues to sell generic opioids.[864]

I am further informed Teva USA and Cephalon ran a combined SOM program after Cephalon's acquisition in 2011, and I am informed that both entities operated as a single unit with regard to the marketing, sale and distribution of Cephalon's name-brand opioid products. After Teva Ltd. acquired the Actavis Generic entities in 2016, those entities were folded into the Teva USA SOM program.

Based on the evidence I have reviewed in this case, Teva did not maintain effective controls against diversion via an adequate SOM program and failed to take reasonable steps to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. The only written standard operating procedure identified by Teva that in any way concerns suspicious order monitoring is SOP-0013489 ("Order Management"), which was approved for Cephalon on June 1, 2009 prior to its acquisition by Teva. Under those procedures, orders by customers that are not pre-authorized by Cephalon were investigated as potentially suspicious and investigated by the Logistics Manager or designee and the order is reported to the DEA if follow up suggested it is suspicious. Unauthorized customers that wished to proceed with their orders were required to open new accounts.[865]

2. In 2012, Teva hired Ronald Buzzeo and Cegedim Relationship Management to perform an onsite review and assessment of Teva's then current SOM system at Teva's North Wales, Pennsylvania site.[866]

3. On September 25, 2012, Buzzeo and Cegedim submitted their report[867] to Teva's Director of DEA Compliance, Colleen McGinn.

4. The Buzzeo report noted Teva had a "rudimentary" SOM system with a process for opening new accounts and pended orders using a program known as "SORDS (Suspicious

[863] Depo. of Marchione, 23:16-22; 68:17-69:12; Ex. 5; Ex. 32.
[864] Watson Pharmaceuticals acquired Actavis Group in 2012, and changed its name to Actavis plc. In 2016, Allergan plc completely shed its generic drug business and sold the Actavis Generic entities and its other generic assets to Teva Ltd. for $40.5 billion. *See also* Depo. of Hassler, 34:11-43:19; Ex. 4; 56:11-58:9; 59:10-63:20; Ex. 5.
[865] Depo. of Hassler, 72:11-76:21; Ex. 7.
[866] Depo. of McGinn, 236:15-237:23; 243:12-266:1; Ex. 15.
[867] MDL_A_01060005 (9/25/12 Buzzeo/Cegedim Report).

ORDerS), which the report concluded "is not sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices." [868]

5. The Buzzeo report further noted Teva had never identified a suspicious order or reported a suspicious order to the DEA, and had "no program to review 'downstream distribution' of Teva products, and there were "no formal Standard Operating Procedures or official guidelines …."[869]

6. The Buzzeo report[870] made a number of further findings and recommendations including the following:

    a. Teva's current due diligence on new and existing customers was inadequate. The report recommended expanding the amount of initial due diligence for existing and potential customers to include at a minimum further initial client screening including a questionnaire, an on-site visit and internet research on the customer.
    b. Teva's SORDS system was inadequate to properly evaluate for suspicious orders. That system "rel[ied] heavily upon the use of standard deviations for identifying orders that [were] possibly suspicious." Under this system, any order that was in excess of three standard deviations above the mean was "pended" for further investigation, which the report noted only identified three out of 1000 orders and failed to identify orders of unusual frequency or pattern. The empirical rule is that a system using three standard deviations would identify only 0.3% of orders as requiring further investigating. The report recommended immediate changes to SORDS including reducing the limit from three to two standard deviations, as well as certain long-term solutions to improve their monitoring system.
    c. Teva's investigation of "pended" orders was not well-documented. The report recommended a process for Teva to investigate and document its investigation and to access information in the course of such investigation.
    d. Teva did not have standard operating procedures or official guidelines for the operation of an SOM program, and the procedures followed did not have sufficient depth for opening new accounts and reviewing pended orders. The report recommended developing such written procedures and guidelines.
    e. Additional recommendations included developing, incorporating and using information "regarding what their wholesaler/distributor customers sell further 'downstream;'" putting in place SOM programs for Teva's manufacturing sites; and addressing state regulations.

[868] MDL_A_01060005 (9/25/12 Buzzeo/Cegedim Report).

[869] MDL_A_01060005 (9/25/12 Buzzeo/Cegedim Report).

[870] MDL_A_01060005 (9/25/12 Buzzeo/Cegedim Report).

7. After the report was submitted, Teva decided to develop and operate a new SOM system internally rather than retain outside third parties to assist in this process. Teva first hired Kevin Kreutzer from AmerisourceBergen in January 2013 to design, develop and operate the Teva SOM program. Mr. Kreutzer was terminated by Teva after two and a half months on the job. Prior to that time, Teva never had an individual who was specifically assigned to manage the suspicious order monitoring program.[871] Teva next hired Joseph Tomkiewicz from AmerisourceBergen in January 2014 to design, develop and operate the Teva SOM program. Mr. Tomkiewicz was a corporate investigator for AmerisourceBergen from 2008 to 2012, performing new customer due diligence and suspicious order review, and was its Diversion Program Manager in 2013 before leaving for Teva.[872]

8. Tomkiewicz ultimately designed a SOM program which he coined "DefOps," which means "Defensible Operations," which Tomkiewicz testifed was named that way because it was intended to be a system defensible if there was an audit by state pharmacy organizations or the DEA.[873] The first version of the DefOps system was not put in place until March 1, 2015 to replace the SORDS system.[874]

9. The written SOPs for the system were drafted and approved internally by Teva in August 2014, nearly two years after the Buzzeo/Cegedim report recommended Teva have written SOM procedures in place.[875] The initial SOM SOPs and later revisions are as follows:[876]

SOP No.	SOP Name	SOP Date	BATES
8279	SOM – Customer Due Diligence	8/1/2014	TEVA_MDL_A_02660924
8280	SOM – Customer Site Visits	8/1/2014	TEVA_MDL_A_02660932
8277	SOM – DEA Order Holds	8/1/2014	TEVA_MDL_A_02660892
8278	SOM – Do Not Ship List	8/1/2014	TEVA_MDL_A_01061094
8489	SOM – DEA Order Holds – Locations Other Than New Britain, PA, and North Wales, PA	10/1/2015	TEVA_MDL_A_03160173
8277	SOM – DEA Order Holds	6/18/2018	TEVA_MDL_A_01158453
8278	SOM – Do Not Ship List	6/18/2018	TEVA_MDL_A_01158463
8279	SOM – Customer Due Diligence	6/18/2018	TEVA_MDL_A_01158470
8280	SOM - Customer Site Visits	6/18/2018	TEVA_MDL_A_01158479

[871] 12/14/18 McGinn Depo., pp. 289-90.

[872] Depo. of McGinn, 289:18-299:4; 300:8-319:5; 320:11-21; 322:17-24; 323:11-18; Ex. `2; Ex. 19; Ex. 20.; Tomkiewicz Dep. p. 139:19-140:4; 141:11-142:7; 142:24-143:11; 144:4-6; 217:10-218:16.

[873] 11/28/18 Tomkiewicz Depo., pp. 267-77 (DefOps System); pp. 319-29 (2015 internal audit findings).

[874] 11/28/18 Tomkiewicz Depo., p. 266.

[875] 11/28/18 Tomkiewicz Depo., p. 243; *see also* 11/16/18 Hassler Depo., Exh. 7 (SOM SOP Chart).

[876] 11/28/18 Tomkiewicz Depo., pp. 244 and 358-58; 11/16/18 Hassler Depo, pp. 72-78 and Exh. 7 (SOM Chart); MDL_A_01060005 (9/25/12 Buzzeo/Cegedim Report).

10. Teva's DEA Compliance Department only has a single SOM manager, Joseph Tomkiewicz, and a single employee, Mathew Benkert, reporting to Mr. Towkiewicz to identify, investigate and release suspicious orders and report them to the DEA.[877]

11. [redacted][881]

12. Teva's DefOps and the prior SORDs system relied and continues to rely on its sales department to assist in conducting an investigation into a potentially suspicious order. Teva's SOM operating procedures provide that the "Suspicious Order Oversight Team" includes "a representative from DEA Compliance, Customer Service, and Customer Account Management"; that if an order is not consistent with a customer's previous order that Customer Service "will contact the customer for clarification about the quantity ordered" and further "Customer Service will contact the customer to request the reason for the increase change in ordering pattern"; and "if a customer does not satisfactorily respond to a Customer Service inquiry, the appropriate Sales Associate will be contacted and instructed to obtain an explanation from the customer."[882] The involvement of Teva's sales department in the SOM investigation process creates a conflict of interest.[883]

13. This conflict is illustrated by the involvement of Teva's sales department in the DEA Compliance Department's investigation of a potentially suspicious order of Teva's generic oxycodone product wherein the DEA Compliance Department found suspicious activity with regard to the order, but did not report the order to the DEA and shipped the order

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[877] 11/28/18 Tomkiewicz Depo., pp. 204-05.

[878] 11/28/18 Tomkiewicz Depo., pp. 379-89; *see also* 11/16/18 Hassler Depo., pp. 141-49.

[879] 11/28/18 Tomkiewicz Depo., p. 387.

[880] 11/28/18 Tomkiewicz Depo., p. 387.

[redacted]

[882] TEVA_MDL_A_01158453 (Teva 2018 Standard Operating Procedure 8277, "Suspicious Order Monitoring - DEA Order Holds").

[883] *See* 11/28/18 Tomkiewicz Depo., pp. 393-407 and Exh. 18, Slide 20 (Tomkiewicz Powerpoint slide entitled "Managing Conflicts"); *see also* 1/15/19 Boyer Depo., pp. 124 and 227 (testifying that key competitive advantage for generic drug manufacturers is to ensure a continuous and uninterrupted supply of those products)..

without sufficient documentation of a basis to dispel that suspicion. The documents and deposition testimony by Teva's SOM manager, Mr. Tomkiewicz, reflect Teva's DEA Compliance Department identified a potentially suspicious order by Publix Supermarkets for its in-store pharmacies made through Anda, Inc., one of Teva's wholesaler customers. Per Teva's procedures, Mr. Tomkiewicz requested that the Teva Sales Department obtain further information about their top 10 stores by oxycodone tablet volume; a breakdown by SKU number of their ER and IR volume; and a list of the top 5 prescribers for each of the 10 locations. Mr. Tomkiewicz identified a number of red flags with regard to the order including with regard to their Florida location, sales volume, and emphasis on the higher doses.[884] Upon receipt of further information and upon further investigation and analysis, Mr. Tomkiewicz found that 9 of the 10 pharmacies had ordered between 25.4% to 58.6% of the highest strength IR oxycodone dose (30 mg), and for 8 of those 9 the 30 mg was the largest percentage of sales.[885] In contrast, for the remaining pharmacy (which was near a cancer center) the lowest dose (5 mg) was the largest percentage of sales (42.3%) and the highest 30 mg dose sales was only 5%.[886] Mr. Tomkiewicz's investigation and analysis of the top 5 prescriber information showed substantial pill mill activity associated with a number of those prescribers.[887] In the course of Mr. Tomkiewicz's investigation, Teva's Vice President for Commercial Operations, Christine Baeder, Teva's Director of National Accounts, Jocelyn Baker, and Teva's Senior Director for Trade Customer Service, exerted substantial pressure on the DEA Compliance Department and on Mr. Tomkowicz personally to release the full order to Publix and not to report the order to the DEA.[888] The Teva Sales Department took the view that the dispensing data was "good enough for them," and that "Publix has 0.8% overall market share and we (Teva) are trying to capture generic oxycodone market share."[889] Teva ultimately shipped the Publix order and did not report it to the DEA.[890] Teva should have reported the Publix order to the DEA and should not

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[884] 11/28/18 Tomkiewicz Depo., pp. 417-21 and Exh. 17 thereto. The "serious red flags" identified by Tomkiewicz in his October 16, 2015 (Exh. 17) included the following:

> "1. This is a high strength oxycodone ultimately going to Florida, a well established hot spot for oxycodone abuse in the U.S.
>
> 2. The total quantities in the Publix forecast put them significantly above their peers as far as size and class of trade are concerned.
>
> 3. The breakdown by strength with an emphasis on 40 mg does not appear to be normal for a retail pharmacy."

[885] 11/28/18 Tomkiewicz Depo., pp. 440-45 and Exh. 22 thereto (pp. 1-2).

[886] 11/28/18 Tomkiewicz Depo., pp. 442-43 and Exh. 22 thereto.

[887] 11/28/18 Tomkiewicz Depo., pp. 445-51 and Exh. 22 thereto (pp. 1-2).

[888] 11/28/18 Tomkiewicz Depo., pp. 408-59 and Exhs. 17 to 22; *see also* example of customer service involvement in Exh. 23 (customer service representative releasing order). In addition, Teva's first SOM Manager, Kevin Kreutzer, testified he was terminated because he had contacted a downstream customer during an SOM investigation. (11/27/18 Kreutzer Depo., pp. 269-270.)

[889] 11/28/18 Tomkiewicz Depo., pp. 440-45 and Exh. 21 thereto

[890] 11/28/18 Tomkiewicz Depo., pp. 408-10.

have shipped the order. There is no written record of any steps that were taken by Publix or any follow up by Teva after the order was shipped to ensure Teva's oxycodone was not diverted for inappropriate uses.

14. Teva Ltd., which I am informed is Teva's parent company in Israel, audited Teva's DEA compliance department in 2015 and prepared a report critical of the department and the SOM program.[891] The report stated that Teva investigated 10,000 line orders per month of Schedule II products; of these 10,000 orders, 95% were automatically released. Only 5% of the orders were placed on hold to be manually checked.[892] The report found the DEA Department was in "non-compliance with DEA requirements" and was at "High Risk" of DEA regulatory action, and the SOM program was at "Moderate Risk" for such action.[893] For the SOM program, the report focused primarily on the fact that suspicious orders were cleared through the decisions of a single person, which exposed the system to the risk of mistaken releases.[894] Ultimately, the recommendation was not implemented.[895]

15. I am informed that Teva's 2018 SOM SOPs remain in effect, and apply to all Teva Ltd. U.S. subsidiaries, including Teva USA, Cephalon and the acquired Actavis Entities. The 2018 written standard operating procedures are essentially the same as the initial SOM procedures that were approved by Teva in 2014.[896]

16. Teva's current DEA Compliance Senior Director affirmed the following at her deposition:
    - At all times Teva sold and distributed opioid products, Teva had a duty to have a suspicious order monitoring program in place.[897]
    - Teva has a duty to investigate if they find suspicious opioid orders from their customers.[898]
    - If Teva does not have a suspicious order monitoring system or fails to have one that is effective in identifying suspicious orders then they have breached their duty and responsibility according to DEA regulations.[899]
    - If Teva fails to investigate potentially suspicious orders then they have breached their duty.[900]

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[891] 11/28/18 Tomkiewicz Depo., Exh. 14 (2015 Internal Audit Report), [TEVA_MDL_A_02475564].

[892] 11/28/18 Tomkiewicz Depo., pp. 319-29 (calculations re: orders flagged, investigated, and released).

[893] TEV_A_MDL_A_02475564 (2015 Internal Audit, pp. 12, 18 and 22 of PDF).

[894] TEV_A_MDL_A_02475564 (2015 Internal Audit, pp. 18 and 22 of PDF).

[895] 11/28/18 Tomkiewicz Depo. pp. 329-35.

[896] Hassler Dep. p. 72:11-76:21, Exh. 7; Tomkiewicz Dep. p. 220:20-221:20; 227:9-228:7; 231:10-13; 241:12-244:3; 244:5-246:9; 285:22-287:6; 301:7-12; 358:10-359:8; McGinn Dep. p. 323:1-10.

[897] 12/14/18 McGinn Depo., p. 125.

[898] 12/14/18 McGinn Depo., p. 128.

[899] 12/14/18 McGinn Depo., p. 129.

[900] 12/14/18 McGinn Depo., p. 131.

- If Teva did not follow the DEA regulations and have effective systems in place to prevent diversion, then they contributed to the opioid epidemic.[901]

17. I have not seen any suspicious orders were reported by Teva to the DEA prior to 2013, and from 2013 to 2018 the following numbers of suspicious orders were reported to the DEA by Teva:[902]

2013: 1

2014: 1

2015: 5

2016: 0

2017: 5

2018: 16

Without restating every finding laid out above, I conclude Teva's SORDs system in place until 2015 was inadequate for multiple reasons, including the reasons stated in the Buzzeo/Cegedim report. Teva also took nearly two years after the Buzzeo report (August 2014) to approve written procedures, and two and one-half years after that report (March 2015) to institute a new SOM system. Teva also did not implement the use of chargeback or 867 data to identify suspicious orders by downstream customers until 2015 and 2017 respectively. Teva also designed an in-house SOM program I am informed without overview, assistance or review from outside consultants, but rather relied primarily on a single individual, Joseph Tomkiewicz, for the design and implementation of the program.[903] Teva's SOM program also relies on and involves substantially the Teva sales department, which has clear financial conflicts, in its SOM investigation and system, and does not provide adequate separation of its SOM employees from the sales department in their investigation and decision-making with regard to decisions to suspend and report suspicious orders. Teva only identified 28 suspicious order reports to the DEA in its responses to interrogatories after the Buzzeo/Cegedim Report, mostly for smaller distributors and many of which consisted of multiple reports for the same distributors.

[901] 12/14/18 McGinn Depo., p. 135.

[902] *See* 1/7/19 Responses and Objections of Defendants Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, Actavis Pharma, Inc., and Watson Laboratories, Inc. to Plaintiffs' Third Set of Interrogatories, Response to Interrogatory No. 32 (at p. 11) and Appendix A thereto (listing bates numbers for DEA reports). Many of the DEA reports identified in Appendix A appear to be duplicates.

[903] McGinn Dep. p. 323:11-324:4; 341:5-13; 395:2-6; Tomkiewicz Dep. p. 216:15-219:18; 268:8-13; 320:4-12

G. Insys[904]

Based on the evidence I have reviewed in this case, Insys failed to maintain effective controls to prevent diversion by failing to take reasonable steps to prevent its products from being diverted. This conclusion is based on the following facts, as established by the evidence in this case and as elaborated on in more detail throughout this section:

1. From the launch of Subsys in 2012, the majority of Insys' sales were to wholesale pharmaceutical distributors, which would sell Subsys to pharmacies, hospitals and other customers. In 2012, three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, comprised approximately [redacted] of the total gross sales of Subsys. These wholesalers comprised a significant portion of the distribution network.[905]

2. According to Insys, these distributors implemented SOM programs that addressed what had been set forth by the DEA. Distributors did not provide any SOPs of their programs but told Insys that they: review the size of the store and its product mix; review schedule II controlled substances (CII) vs. traditional drug dispensed; review the size patterns around CII medications; timing of CII orders; location of the facility, as well as some geographic areas that are 'hot spots' for diversion. Insys conducted no independent investigation regarding the distributors' SOM programs at all. In spite of all this, distributors were allowed increases in Subsys if a specific reason for the requested increase was communicated.[906]

   Insys never incorporated any of the relevant transactional sales data that could assist in disclosing diversion into its real-time SOM system, including, IQVIA, chargeback data, sales representatives' tips, or even the Integrichain data that its Sales Operations team was using in order to sell its opioid products and track stocking at the pharmacy level. In spite of this, I am informed that Insys used this information to spot high prescribers and to ensure that wholesalers were stocking targeted pharmacies with Subsys, and that Insys was also buying third party data from Integrichain.
3. Insys had a Trade and Distribution department tasked with ensuring the availability of Insys products while also maintaining effective controls to prevent diversion.[907] I am informed that Dion Reimer is the former Insys employee, is the person most knowledgeable with

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[904] Multiple depositions of Insys witnesses have been stayed pending a criminal trial in the District of Massachusetts. I reserve the right to supplement these opinions as any new information become available.

[905] INSYS-MDL-007657600

[906] *Id*. at FN1

[907] INSYS-MDL-001668983

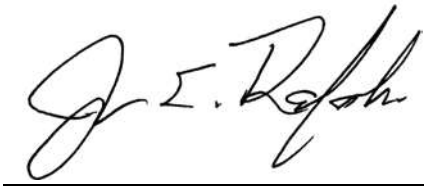
respect to the SOMs policies at Insys. However, Mr. Reimer's deposition has been stayed until after the criminal trial by the DOJ in the District of Massachusetts because Mr. Reimer is on the DOJ's witness list.

4. Nevertheless, deposition testimony by current Insys employees has confirmed that Insys failed to implement any SOM system or maintain any SOM protocols until 2018.[908]

5. This failure to conduct any sort of SOM process continued despite the fact that Insys was conscious that it habitually lost track of inventory in its downstream customers like Linden Care.[909] For other wholesalers where they did not receive inventory level reports, Insys estimated the levels. Significant differences between actual and estimated inventory levels often resulted. Many times, distributor purchases exceeded customer demand, a situation that creates a risk of diversion.

In my expert opinion, Insys failed to conduct any SOM process, even failing to track for orders of unusual size. The lack of any SOM program did not satisfy DEA requirements to detect and investigate suspicious orders. Insys failed to maintain effective controls to prevent diversion.

I reserve the right to amend or supplement my opinions in this matter considering any new or additional information.



James E. Rafalski

Date: April 15, 2019

[908] *See* Deposition of James Doroz at 53; 118; 251. *See* also Thomas Udicious Tr. at 19; 44.

[909] *See* James Doroz Tr. at 221.